SP-10

Spirometer

SP-10 User Guide

Artide Number 2.510277a

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Schiller®

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DECLARATION OF CONFORMITY

Spirometer:	**SP-10**
Serial numbers starting with:	531.
Year of manufacture:	1995 Onwards

We, the undersigned, hereby declare that the medical device (class IIa) specified above conforms with the essential requirement listed in Annex 1 of EC Directive 93/42/EEC.

This declaration is supported by:

Certificate of approval No:	11425-01	ISO 9001 (Rev.1994) EN 46001 by SQS
	45112-60-00	ISO 9001/08.94, EN 46001 / 12.93 by DEKRA
and	45112-16-00	Annex II, Section 3 of the Directive 93/42/EEC (30.04.1995)

CE 0124

Baar (Switzerland) 03.07.1996

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Disclaimer

The Information in this guide has been carefully checked for reliability; however no guarantee is given as to the correctness of the contents and WELCH ALLYN SCHILLER makes no representations or warranties regarding the contents of this manual. We reserve the right to revise this document and make changes in the specification of the product described within at any time without obligation to notify any person of such revision or change.

Trademarks

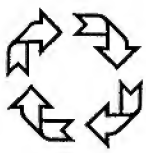
WELCH ALLYN SCHILLER and SP-10 are registered trademarks of WELCH ALLYN SCHILLER. All trademarks are the property of their owners.

Terms of Warranty

WELCH ALLYN SCHILLER warrants the SP-10 Spirometer, when new, to be free of defects in material and workmanship and to perform in accordance with manufacturer`s specifications for the period of three (3) years from the date of purchase from Welch Allyn or it`s authorized distributors or agents. Accessory items such as electrodes, batteries and cables are limited to a warranty of 90 days from the date of purchase from Welch Allyn or its authorized distributors or agents. Welch Allyn will repair or replace any components found to be defective or at variance from manufacturer`s specifications within this time at no cost to the customer. It shall be the purchasers responsibility to return the instrument to Welch Allyn or an authorized distributer, agent or service representative. This warranty does not include breakage or failure due to tampering, misuse, neglect, accidents, modifications or shipping. This warranty is also void if the instrument is not used in accordance with manufacturer`s recommendations or if repaired by other than Welch Ally or an authorized agent. Purchase date determines warranty requirements. No other express warranty is given.

This equipment has been tested and found to comply with the limits for a class A digital device, pursuant to both Part 15 of the FCC (Federal Communications Commision) Rules and the radio interference regulations of the Canadian Department of Communications. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with this instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Disposal Instructions and Battery Care



- DO NOT DISPOSE OF THE BATTERY BY FIRE OR INCINERATOR - DANGER OF EXPLOSION
- DO NOT ATTEMPT TO RECHARGE THE BATTERY - DANGER OF EXPLOSION
- DO NOT OPEN THE BATTERY CASING - DANGER OF ACID BURN

Only dispose of the battery in official recycling centres or municipally approved areas. Alternatively used batteries can be returned to Schiller AG for disposal.

Unit Disposal Instructions

Units no longer required can be returned to Schiller AG for disposal. Alternatively dispose of the unit in municipally approved recycling centres.

Power Supply

The mains connection is on the rear of the unit.

The power supply voltage is set by the factory for100-115V(nom. 110V) or 220-240V (nom. 230V) working. The setting is indicated by the indented metal strip on the fuse panel. Contact your dealer if the voltage needs to be changed.

The mains indicator lamp on the keyboard is always lit when the unit is connected to the mains supply. The unit can either be operated from the mains supply or from the built-in rechargeable battery. The power source is indicted on the top line of the LCD.

Changing a Mains Fuse

If it is necessary to change a fuse, always replace with the correct rating i.e 2x200mAT for 230V, or 2x400mAT for 110V.

To change a fuse press the two retaining lugs on side of the fuse panel (situated below the mains connector on the back panel. Remove the fuse panel and replace the fuse(s). Click back the fuse panel.

PHYSICIAN'S RESPONSIBILITY

THE SP-10 SPIROMETER IS PROVIDED FOR THE EXCLUSIVE USE OF QUALIFIED PHYSICIANS OR PERSONNEL UNDER THEIR DIRECT SUPERVISION. THE NUMERICAL AND GRAPHICAL RESULTS FROM A RECORDING MUST BE EXAMINED WITH RESPECT TO THE PATIENTS OVERALL CLINICAL CONDITION. THE RECORDING PREPARATION QUALITY AND THE GENERAL RECORDED DATA QUALITY, WHICH COULD EFFECT THE REPORT DATA ACCURACY, MUST ALSO BE TAKEN INTO ACCOUNT.

IT IS THE PHYSICIANS RESPONSIBILITY TO MAKE THE DIAGNOSIS OR TO OBTAIN EXPERT OPINION ON THE RESULTS, AND TO INSTITUTE CORRECT TREATMENT IF INDICATED.

FEDERAL LAW IN THE USA RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

Safety Notices

THIS UNIT IS BF CLASSIFIED ACCORDING TO IEC 601-1.

TO PREVENT ELECTRIC SHOCK DO NOT DISASSEMBLE THE UNIT. NO SERVICEABLE PARTS INSIDE. REFER SERVICING TO QUALIFIED PERSONNEL ONLY.

DO NOT USE THIS UNIT IN AREAS WHERE THERE IS ANY DANGER OF EXPLOSION OR THE PRESENCE OF FLAMMABLE GASES SUCH AS ANAESTHETIC AGENTS.

THIS PRODUCT IS NOT DESIGNED FOR STERILE USE.

THIS PRODUCT IS NOT DESIGNED FOR OUTDOOR USE.

SWITCH THE UNIT OFF BEFORE CLEANING AND DISCONNECT FROM THE MAINS.

DO NOT, UNDER ANY CIRCUMSTANCES, IMMERSE THE UNIT OR CABLE ASSEMBLIES IN LIQUID.

THE DEVICE MUST ONLY BE OPERATED USING BATTERY POWER IF THE EARTH CONNECTION IS SUSPECT OR IF THE MAINS LEAD IS DAMAGED OR SUSPECTED OF BEING DAMAGED.

DO NOT USE HIGH TEMPERATURE STERILISATION PROCESSES (SUCH AS AUTOCLAVING). DO NOT USE E-BEAM OR GAMMA RADIATION STERILISATION.

DO NOT USE SOLVENT CLEANERS

USE ONLY ACCESSORIES AND OTHER PARTS RECOMMENDED OR SUPPLIED BY WELCH ALLYN SCHILLER. USE OF OTHER THAN RECOMMENDED OR SUPPLIED PARTS MAY RESULT IN INJURY INACCURATE INFORMATION AND/ OR DAMAGE TO THE UNIT.

THE SP-10 COMPLIES WITH EMC REGULATIONS FOR MEDICAL PRODUCTS WHICH AFFORDS PROTECTION AGAINST EMISSIONS AND ELECTRICAL INTERFERENCE. HOWEVER SPECIAL CARE MUST BE EXERCISED WHEN THE UNIT IS USED WITH HIGH FREQUENCY EQUIPMENT.

SP-10 User`s Guide

This User`s Guide gives instructions on how to operate the unit and provides an overview of all the basic functions in an easy and simple to use format. The procedures are presented in a logical, step-by step way to enable the user to quickly and easily familiarise themselves with unit operation. Detailed medical information is excluded from this guide except where necessary to operate the unit or understand the results.

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CE 0124 93/42/EEC Medical Devices:
0124 `Notified Body` DEKRA AG

CHAPTER 1

Introduction and System Settings

INTRODUCTION

The SCHILLER SP-10 is a sophisticated, compact work station for pulmonary diagnosis with the following characteristics:

- Multiple operation possibilities, thanks to low weight and battery power.
- LCD display.
- Menu guidance provided for ease of operation.
- The SP-10 is capable of working in four measurement modes as follows:

  Forced Vital Capacity (FVC-Test)

  Vital Capacity (VC-Test)

  Expired or Minute Ventilation (MV-Test)

  Maximum Voluntary Ventilation (MVV-Test)
- Additional options enable resistance testing and blood oximetry diagnosis to be carried out.
- The test results are displayed on the integral LCD and recorded on the built-in thermal printer.
- The open pneumotacho transducer SP-110, with disposable mouthpiece, is used for respiratory measurement.
- As options, WELCH ALLYN offers instead of the SP-110, either the SP-150 with disposable measurement unit integrated inside the mouthpiece or the SP-20.
- As further option in combination with resistance tests the SP-110/R flow sensor is necessary. This sensor can also be used for normal pulmonary function tests.
- RS-232 and RS-422 interfaces are provided for data transmission and for the connection to the SCHILLER PC-based data management program (SEMA) for validation and archiving of recorded data.
- The unit also has a facility for the connection of an external video monitor.

INTRODUCTION

Getting Started

Location

Do not keep or operate the apparatus in a wet, moist, or dusty environment. Also, avoid exposure to direct sunlight or heat from other sources.

Do not allow the unit to come into contact with acidic vapours or liquids, as such contact may cause irreparable damage.

The unit should not be placed near X-ray or diathermy units, large transformers or motors of any kind.

WARNING:

THIS APPARATUS SHOULD NOT BE OPERATED IN AREAS WHERE THERE IS ANY DANGER OF EXPLOSION.

Potential Equalisation (Grounding)

Attach the yellow/green ground lead (supplied with the unit) between the potential equalisation stud of the SP-10 (situated on the rear panel) and the hospital/building common ground.

The connection for the potential equalisation is marked with the ⏚ symbol.

Switch the Unit On/Off

The SCHILLER SP-10 can be operated either from the mains supply or from the built-in batteries.

To operate the unit from the mains, connect the power cable to the mains supply and plug it into the connection on the rear of the unit.

The SCHILLER SP-10 is switched on or off with the **I/O** power switch located above the mains connection on the rear of the unit (green lamp is lighted when on). If the unit is switched on and the ON key is not pressed, the battery is charged if necessary (yellow lamp is lighted).

The SP-10 can remain connected to the mains supply without damage.

To start the functions the ON key has to be pressed. If that is done without switching the unit on with the I/O switch, the SP-10 runs on battery power (yellow lamp is lighted).

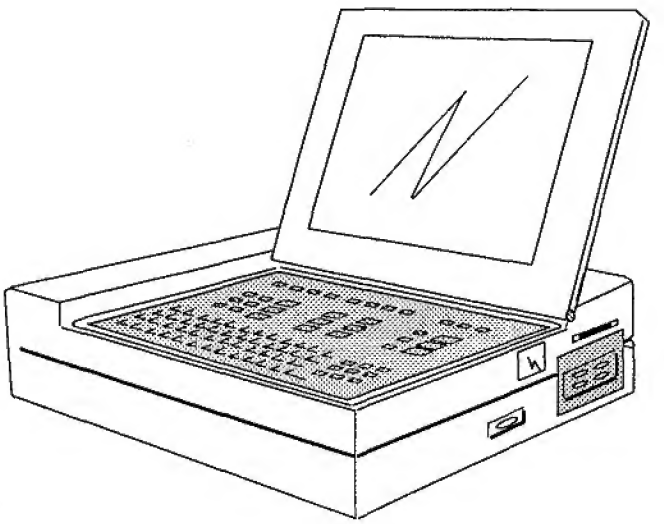
A self-test of the unit is automatically initiated every time the unit is switched on.

BEFORE SWITCHING THE UNIT ON, ENSURE THAT THE FLOW SENSOR IS PLUGGED IN. IF THE SENSOR IS NOT CONNECTED, A MESSAGE APPEARS TO CONNECT THE SENSOR. THE UNIT MUST FIRST BE SWITCHED OFF, THE SENSOR CONNECTED AND THE UNIT SWITCHED ON AGAIN.

THE FLOW SENSOR CAN ONLY BE CONNECTED WHEN THE UNIT IS SWITCHED OFF. IF ANY KEY IS PRESSED WITH THE SENSOR NOT CONNECTED THE UNIT AUTOMATICALLY SWITCHES OFF.

INTRODUCTION

Overview of the SCHILLER SP-10



The main operating and connection modules of the SCHILLER SP-10 are as follows:

Keyboard	The keyboard comprises the general function and control keys, and the alphanumeric keys for data entry.
LCD Screen	The LCD screen displays the pulmonary traces and certain operating and status information. Under operator control the display also gives menu options and displays operator entered data. The display is folded down when not in use.
Thermal Printer	The printer provides the hard copy of test results.
Right-hand Side Panel	The side panel contains the Spirometry connector and the RS serial connectors.
Left-hand Side Panel	This panel contains the paper tray and (below the paper tray) the program pack.
Back Panel	The back panel contains the video monitor connector and the mains connector with on/off switch, voltage selector and mains fuse.

DISPLAY

Liquid Crystal Display (LCD)

The liquid crystal display (LCD) performs both as a real-time monitor and as an alphanumeric display for menu selection, data input and the provision of important information.

Depending on the function, the displayed information will vary but the screen is normally divided into three main parts:

Top of the screen	status and operating information are permanently displayed.
Right side	test results are displayed.
Left side	the display is divided into the following five fields from the top: • Date and Time • Function / Battery capacity in % • Status of CAPS key • Alert field
Central Part of Display	In the central part of the display the test curve of the selected test is displayed.
Lower Part of Display	The very bottom line gives the function key for the next step.

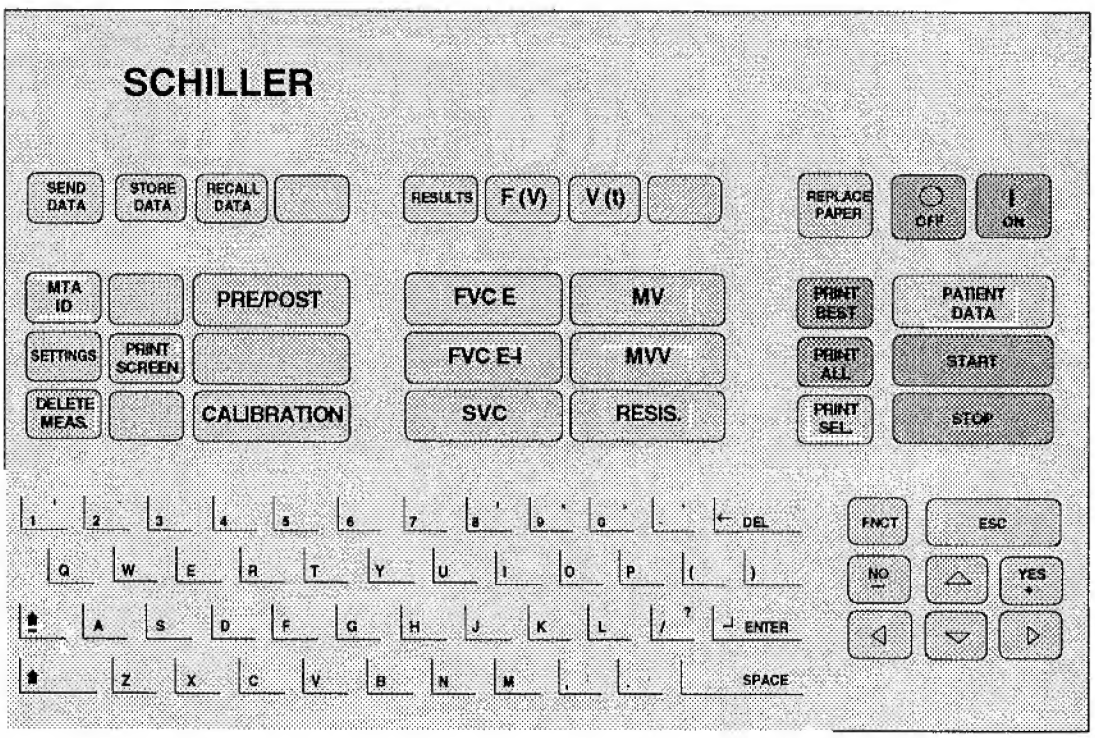
Adjusting the Contrast

The contrast can be adjusted by means of the LCD knob located on the right-hand side of the unit. Visibility is best when the display is fully illuminated.

KEYBOARD

The keyboard is divided into the following functional sections:

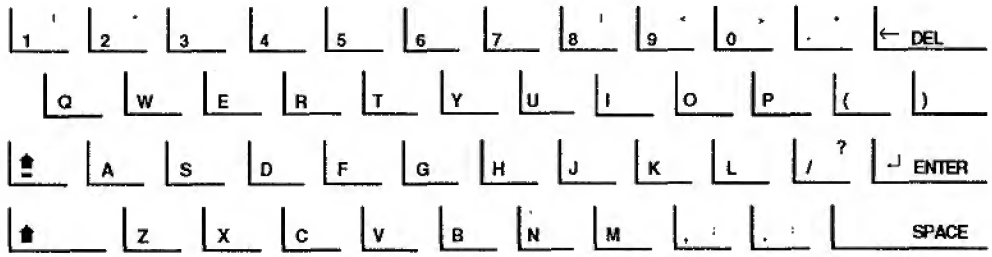
- alphanumeric keypad
- menu control keys
- control and function keys
- test function keys
- general purpose keys



KEYBOARD

Alpha Numeric Keyboard

The alphanumeric keyboard serves as a normal keyboard for data input and is arranged as follows:



Special keys of the alphanumeric keyboard:

Key	Function
← DEL	Delete character to the left of the cursor.
↵ ENTER	Confirm entry or selection.
SPACE	Enter blank space into the text.
⇧	When pressed simultaneously with a letter key it activates the upper case letter. When pressed simultaneously with a number key it activates an alternative symbol set.
⇪	Toggle key to set lower case or upper case letters. The Caps Lock key status is indicated on status information field on the right-hand side of the screen.

KEYBOARD

General Purpose Keys

The general purpose keys are:

call up main menu / return to monitor mode

return to previous menu

change setting / disable command

change setting / enable command

move the cursor up / down

move cursor to left / right

KEYBOARD

Control and Function Keys

The control and function keys are:

I ON	switch unit on
O OFF	switch unit off
REPLACE PAPER	extend / retract paper tray
PATIENT DATA	enter patient data
START	start selected test
STOP	stop test / move paper to start position
PRINT BEST	print best test result
PRINT ALL	print all test results
PRINT SEL.	select test result for printout
SEND DATA	initiate data transmission
STORE DATA	initiate data storage
RECALL DATA	initiate reception mode
MTA ID	enter details of medical assistant
SETTINGS	display general settings menu
DELETE MEAS.	delete stored measurement

KEYBOARD

Menu Control Keys

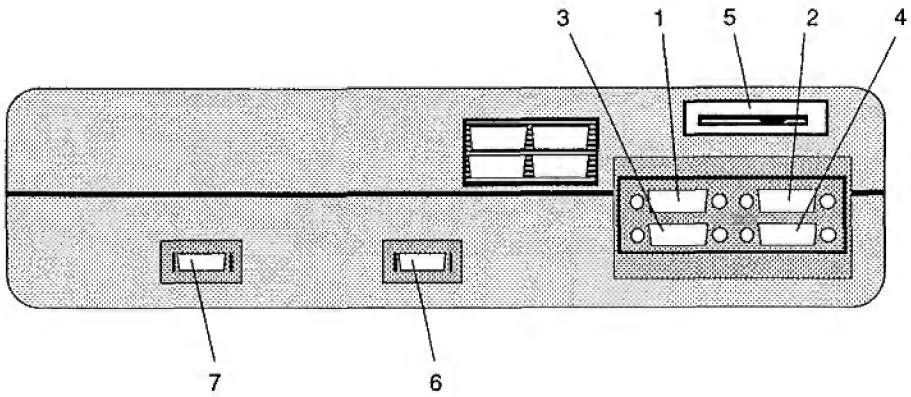
The menu control keys are:

RESULTS	display test results
F(V)	inhalation / exhalation flow (l/s) vs. Volume (l)
V(t)	volume (l) vs. Time (s)
FVC E	Forced Vital Capacity test **(Exhalation only)**
FVC E-I	Forced Vital Capacity test **(Exhalation and Inhalation)**
SVC	Slow Vital Capacity test
MV	Minute Volume (volume in one minute)
MVV	Minute Volume (forced volume in one minute)
RESIS.	Resistance Test (Option)
PRE/POST	pre / post medication test
CALIBRATION	calibration of the unit to environmental conditions

PANELS

The SCHILLER SP-10 has two connector panels. One is located on the back and the other on the right-hand side of the unit.

Right-hand Side Panel



1 RS-232C interface (Port 1) (not used)

2 RS-232C interface (Port 2) (not used)

3 RS-232C interface (Port 3) (for data transmission (e.g. to SEMA)

4 RS-422 interface (Port 4)

5 LCD contrast control

6 Connection for:

SP-110	for pulmonary function measurements with disposable mouthpiece
SP-150	for pulmonary function measurements for single use with disposable flow-sensor
SP-20	for pulmonary function measurements with disposable filter
SP-110/R	for resistance measurements (Option) with disposable mouthpiece

NOTE: The resistance sensor SP-110/R can also be used for pulmonary function (i.e. FVC, VC, MV, MVV) tests.

7 Connection for optional SpO2 sensor

SYSTEM SETTINGS

User Identification

This function enables entry of the name of the physician, clinic or department which will then be given on each printout. The input is stored until overwritten by the user. It is not lost when the unit is switched off. To reach that menu, proceed as follows:

The maximum number of characters is 23.

- Confirm with ↵ ENTER.
- Press ESC to return to the settings menu.

Printout Settings

There are five settings which may need to be made before starting the test, namely the time axis for a printout of the FVC graph, the norm values that are to be used, including of diagnosis on the printout, including of a flow graph on the printout and the sensor that is connected and used for the tests. These settings stay stored until they are selected new.

To reach the menu proceed as follows:

Selections in the menu:

- By pressing key **1**, the time axis for the printout of an FVC graph can be set to:
  - 10 mm/s
  - 20 mm/s
- By pressing key **2** and setting to ON the diagnosis is given as indication on the printout (for explanations, check in the chapter "Value Information" under paragraph "Diagnosis").
- By pressing key **3** and setting to ON the flow graphics is printed.
- By pressing key **4** and setting to ON the PEF values are printed.

SYSTEM SETTINGS

Device Settings

There are seven settings which need to be made before starting the test, namely:

- the sensor that is connected and used for the tests
- calculation basis for norm values
- norm values that are to be used
- race of the patient
- calculation units for weight and size of the patient
- order of date
- measurement units for temperature.

All these settings stay stored until they are selected new.

To reach the menu proceed as follows:

Selection possibilities:

- By pressing key **1**, the flow sensor that is to be used can be selected. The available settings are:
- SP-110 (also used for SP-110/R resistance sensor)
- SP-150
- SP-20

CAUTION:

ENSURE THAT THE CORRECT SENSOR IS SELECTED. MEASURED VALUES CAN BE INACCURRATE WHEN THE INCORRECT SENSOR TYPE IS SET.

- By pressing key **2**, the diagnosis standard can be selected (see Chapter 3).
  - International; for all countries outside the USA and Canada
  - American; for USA and Canada
- By pressing key **3**, the standards used for the various measurement calculations can be selected (see Chapter 3).

CHAPTER 2

Taking Tests

CONNECTING THE FLOW SENSOR / ENTERING USER NAME

IMPORTANT:

CONNECT OR DISCONNECT THE FLOW SENSOR ONLY WHEN THE UNIT IS TURNED OFF.

Each flow sensor is supplied completely with connection cable and plug.

Insert the plug into the socket marked "SPIRO SENSOR" on the right-hand side of the unit.

CAUTION:

EACH FLOW SENSOR CONTAINS A SENSITIVE MEASURING DEVICE AND MUST ALWAYS BE HANDLED WITH CARE. DO NOT ALLOW THE SENSOR TO BE DROPPED OR SUBJECTED TO ANY SUDDEN BLOWS

ENSURE THAT THE CONNECTION CABLE IS NOT TO BE EXPOSED TO ANY MECHANICAL STRESS. WHENEVER DISCONNECTING THE SENSOR, HOLD THE PLUG AND NOT THE CABLE..

The Unit is turned on by pressing [I ON].

If no sensor is connected, the following message appears:

When this message appears, switch the unit off and connect the sensor.

MTA Identification

This function is to register the name of the medical assistant carrying out the recording and must be entered every time the unit is used. The MTA is identified on each printout. Enter the menu as follows:

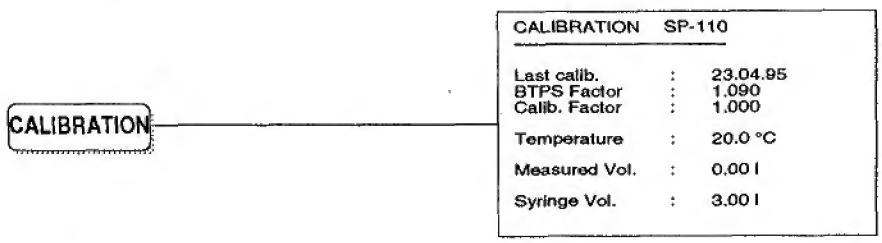
- Confirm with [↵ ENTER].
- Press [ESC] to return to the main menu.

CALIBRATION

The unit must be calibrated:

- before starting the first pulmonary function test of the day
- after a significant temperature change
- after changing the sensor.

Press the calibration key to disaply the calibartion menu:



The following positions are displayed:

Headline	The headline displays the selected sensor. *Ensure that this is the sensor that is connected. If not, select the correct sensor in the Settings menu. Press the SETTINGS KEY and select the 'device settings' option. The sensor type is displayed. Toggle with key 1 between SP-110, SP-150 and SP-20.*
Last Calibration	date of last calibration
BTPS Factor	calculated BTPS (=> **B**ody **T**emperature, Ambient **P**ressure, **S**aturated with water vapour) value
Calibration Factor	calculated value between measured and effective calibration air volume
Temperature	ambient temperature in °C (or °F) dependent on device setting
Measured Volume	air volume measured by the system from the calibration pump
Syringe Volume	Actual (entered) air volume depending on the size of the calibration pump and times the air was pumped through the sensor; e.g. pumping 2 litres 4 times amounts to 8 litres (the recommended volume with a 2 litre pump is 8 litres; with 3 litre pump, 9 litres)

CALIBRATION PROCEDURE

1 Connect the calibration pump to the sensor. Ensure no air leaks.

2 Press the CALIBRATION key. The menu appears as shown opposite.

3 Enter the ambient temperature as prompted

4 Confirm with [↵ ENTER].

5 Press [START] to start the calibration.

6 Wait 1 second.

7 Pump 3 litres, or more, air through the sensor.

NOTE: Make sure that the flow sensor is kept still during the pumping operation.

While pumping, the unit records the actual volume being pumped through the flow sensor and indicates it on the display.

8 Press [STOP] when finished pumping.

9 The cusor is now positioned at syringe volume. Enter the total pumped air volume (depending on the size of the calibration pump and number of times of emptyed; i.e. a litre pump emptyed once = 3 litres, the same pump emtgyed twice = 6 litre).

10 Press [↵ ENTER]. The unit then calculates the calibration factor.

11 The message "Calibration completed" appears on the display

If a printout of the calibaration is required, press [PRINT ALL]. A calibration report is printed with the following information:

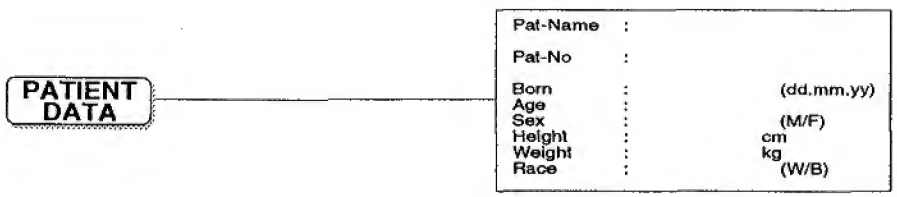
- Measured Volume in litres
- Effective Volume in litres
- Deviation in litres
- Deviation in percent
- Temperature in Celsius or Fahrenheit
- BTPS Factor
- Calibration Factor
- Flow Graph
- Date, Time and Software version

12 Press [FNCT] or [ESC] to return to the main menu.

Note: If the message 'EXCESSIVE DEVIATION! 'appears on the screen after a calibration, it indicates that the difference between the measured volume and the entered volume is too great (<10%). Check the temperature setting, the syringe volume and the entered syringe volume. Reset the calibratioin to bease valuse by pressing 'I' and recalibrate.

PATENT DATA

Each printout is complete with the name and other information concerning the patient. Before beginning a recording, the patient data should be entered. In order to call up the menu for patient data input, proceed as follows:



The following parameters have to be entered:

Pat-Name: Patient name

Pat-No: Patient number

Born: The date of birth has to be entered in figures, separated by a full stop as day.month.year or month.day.year (order depending on unit setup).

Age: The age is calculated by the SP-10 on the basis of the date of birth:

- up to 2 years: number of months;
- up to 6 years: number of years and months;
- over 6 years: number of years

Sex: enter "M" (male) or "F" (female).

Height: in centimetres (or inches, depending on unit setup).

Weight: Weight in kilogrammes (or pounds, depending on unit setup).

Race: Enter patients race (depending on unit setup):

W/B: "W" for White, "B" for Black

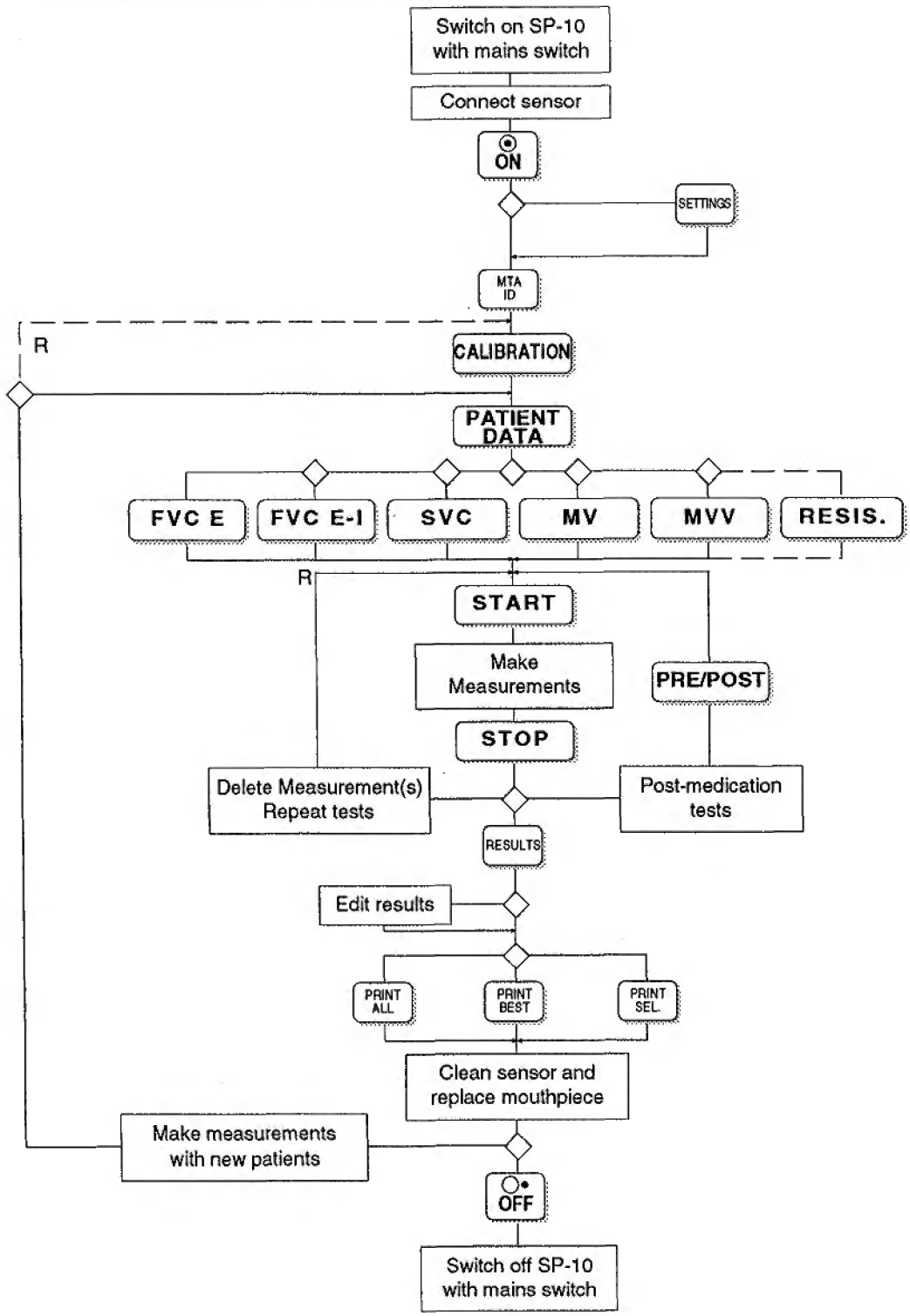
C/H/B/A: "C" for Caucasian, "H" for Hispanic, "B" for Black or "A" for Asian

=> If this position does not appear, "NONE" was selected in the setup (see Chapter 1)

Wrongly typed characters can be deleted before pressing the **ENTER** key by pressing the **DELETE** key. The old content of the line is deleted as soon as the first character is entered. If an error is noticed after **ENTER** has been pressed, complete the entry of all other data and then press the **PATIENT DATA** key and the cursor returns to the first line for data entry. Press **ENTER** until the cursor returns to the line in question and enter the data required. The existing entry is deleted as soon as new data is entered.

PULMONARY FUNCTION TESTS

Schematic Overview of the Test Procedure



PULMONARY FUNCTION TESTS

General Test Procedure

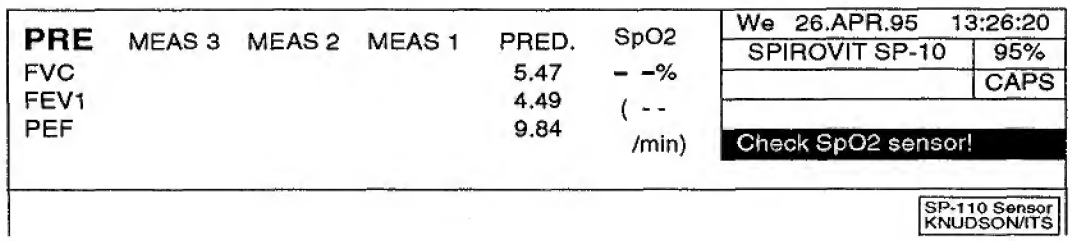
NOTE: Exact descriptions of each step is given in the appropriate section.

Select Test

The required test is selected directly with the appropriate key on the keyboard.

Display

The display indicates the measurements which will be made and gives the predicted results. There are three positions for measurement results enabling several tests to be made. Check if all the necessary information is displayed in the top part of the screen according to the requested setup:



The following information is displayed from left to right (depending on the option that is installed):

- Test information about:
- Premeditation (PRE) or Post-medication (POST) test
- Measured values for all 3 tests (MEAS)
- Predicted (calculated) values according to patient data and norm value settings (PRED.)
- SpO2 value (%) and heart rate (/min) (if SpO2 option is installed)
- Data field containing:
- Date and Time
- Unit Information
- Percentage value of battery capacity
- Status of CAPS key (CAPS = Key locked)
- Possible error message for SpO2 sensor
- A small field on the top right of the chart shows the selected sensor and the set norm values.

The coordinates represent the graph on which the curve will be drawn with the respiratory volume in litres being represented on the vertical axes for the FVC and VC tests (the **relative** respiratory volume in litres for the **MV** and **MVV** tests) and the time in seconds on the horizontal axis.

In the FVC test a second presentation possibility is in form of the flow speed presented on the vertical axis and the flow volume in litres on the horizontal axis. The top part of the screen remains the same.

PULMONARY FUNCTION TESTS

Start Tests

NOTE: The flow sensor must be held quite still and no air should be breathed into the device for at least one second before and after the START key is pressed.

- Press the green key [START] to start the test
- Patient carries out test
- After patient has carried out the test press the [STOP] key to register the result
- Repeat the above procedure for three or more times.

Display Results

With [RESULTS] all the values can be displayed as a table.

Print Tests

By pressing either [PRINT BEST], [PRINT ALL] or [PRINT SEL], a printout is made according to the selection.

The printout contains the patient data, selected norm values, main values for that test, SpO2 percentage rate if option is installed (SpO2), heart rate in beats per minute if option is installed (HR), values for measurement (MEAS), predicted values (PRED.) and percentage rate between measured and predicted values (%PRED.) (PRED. = 100%).

FORCED VITAL CAPACITY (FVC) TEST - EXHALATION ONLY

For this test the patient must exhale as quickly as possible from the time of starting the test.

Inform the patient so, that it is sure that he understands what is required of him.

Note: The FVC test employs the "Back extrapolation" method. If the extrapolated volume is too large (>0.1 litres or 10% of FVC), then a warning appears on the display and a question mark (?) will appear in the FEV, position for that test.

To be able to carry out this kind of Forced Vital Capacity (FVC) test, first press the **FVC E** key.

As soon as the basic screen is displayed, check if all the necessary information is displayed in the top part of the screen according to the requested setup.

Note: The flow sensor must be held quite still and no air should be breathed into the device for at least one second before and after the START key is pressed.

- Press the green **START** key to start the test.

The message "READY FOR MEASUREMENT" appears on the display. As soon as the patient starts to breathe into the flow sensor, the unit begins to record the flow and the corresponding curve is represented on the display. An acoustic "beep" indicates when the break-off point for the measurement has been reached.

Five seconds later, the measurement will be automatically interrupted unless the patient carries on. Measurements will still take place should this break-off point not be reached. Once the test is completed, the measurement results are calculated and given on the display.

Interrupt / End Test

The test can be interrupted at any time by pressing **STOP**.

Delete Measurements

If one of the result columns should be deleted, proceed as follows:

Press the number of that column (e.g. for column 1, press key 1) that is to be deleted. If all the results should be deleted, i.e. all three columns, press key **4**.

FORCED VITAL CAPACITY (FVC) TEST - EXHALATION ONLY

Screen Information

Once the test is completed, the measurement results are calculated and given on the display. When subsequent tests are made, the result with the highest FVC + FEV_1 value will always be saved and given in the right-hand column (MEAS 1).

The result with the lowest FVC + FEV_1 value of the tests already made and stored will be overwritten. An asterisk ("*") indicates the measurement results of the last test made.

NOTE: The marked results correspond to the displayed test curve.

Toggle Screen Information

Two different screen types can be displayed to achieve more information. To toggle the screen, press either V(t) or F(V).

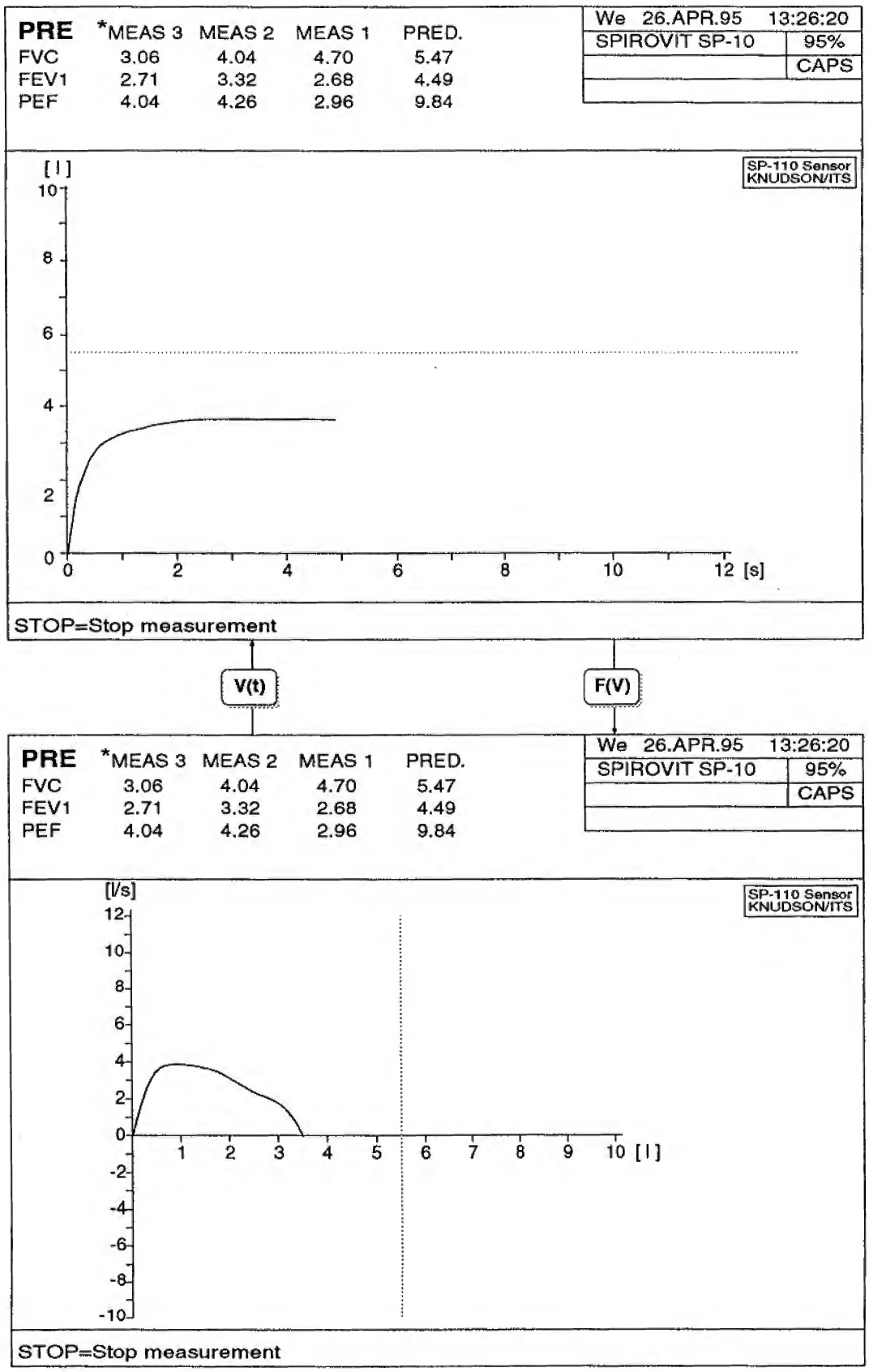
NOTE: The top part of the screen always remains the same.

- With V(t) the chart is given as volume (in litres) in relation of time (in seconds).
- With F(V) the chart is given as flow speed (in litres per seconds) in relation to the air volume (in litres).

The information of the previous screen remains stored and can be displayed with the other key as long as no further test was made.

NOTE: These keys only function with the FVC test.

FORCED VITAL CAPACITY (FVC) TEST - EXHALATION ONLY



FORCED VITAL CAPACITY (FVC) TEST - EXHALATION ONLY

Display Results

To display results of the test, press RESULTS and the following information is displayed:

PRE	*MEAS 3	MEAS 2	MEAS 1	PRED.
FVC	3.06	4.04	4.70	5.47
FEV1	2.71	3.32	2.68	4.49
PEF	4.04	4.26	2.96	9.84

We 26.APR.95	13:26:20
SPIROVIT SP-10	95%
	CAPS

		PRED.	MEAS1	MEAS2	MEAS3	%PRED
FVC	[l]	5.47	4.70	4.04	3.06	86
FEV1	[l]	4.49	2.68	3.32	2.71	60
FEV1/FVC	[%]	83.3	57.0	82.1	88.3	68
FEF.2-1.2	[l/s]	8.23	2.70	3.98	3.88	33
FEF25-75%	[l/s]	4.75	2.13	3.32	3.18	45
FEF75-85%	[l/s]	1.40	1.28	1.67	1.45	91
PEF	[l/s]	9.84	2.96	4.26	4.04	30
MEF75%	[l/s]	8.47	2.92	4.18	3.98	34
MEF50%	[l/s]	5.74	2.23	3.53	3.13	39
MEF25%	[l/s]	2.36	1.59	2.45	2.23	67
FMFT	[s]	---	1.10	0.61	0.48	---
FIVC	[l]	---	---	---	---	---
FIV1	[l]	---	---	---	---	---
FIV1/FIVC	[%]	---	---	---	---	---
FIV1/FVC	[%]	---	---	---	---	---
PIF	[l/s]	---	---	---	---	---
MIF50%	[l/s]	---	---	---	---	---
SVC	[l]	---	---	---	---	---
ERV	[l]	---	---	---	---	---
IRV	[l]	---	---	---	---	---
TV	[l]	---	---	---	---	---
MVV	[l/min]	150.8	---	---	---	---
MV	[l/min]	---	---	---	---	---

Press FNCT or ESC to exit.

Insert / Edit Diagnosis

Press the RESULTS key when in the results menu once more to insert or edit the diagnosis.

Press FNCT or ESC to exit.

FORCED VITAL CAPACITY (FVC) TEST - EXHALATION AND INHALATION

For this test the patient must exhale and inhale as quickly and strongly as possible from the time of starting the test.

Inform the patient so, that it is sure that he understands what is required of him.

NOTE: The FVC test employs the "Back extrapolation" method. If the extrapolated volume is too large (>0.1 litres or 10% of FVC), then a warning appears on the display and a question mark (?) will appear in the FEV, position for that test.

To be able to carry out this kind of Forced Vital Capacity (FVC) test, first press the **FVC E-I** key.

As soon as the basic screen is displayed, check if all the necessary information is displayed in the top part of the screen according to the requested setup.

Carry Out Test

NOTE: The flow sensor must be held quite still and no air should be breathed into the device for at least one second before and after the START key is pressed.

- Press the green **START** key to start the test.

The message "READY FOR MEASUREMENT" appears on the display. As soon as the patient starts to breathe into the flow sensor, the unit begins to record the flow and the corresponding curve is represented on the display. An acoustic "beep" indicates when the break-off point for the measurement has been reached.

Five seconds later, the measurement will be automatically interrupted unless the patient carries on. Measurements will still take place should this break-off point not be reached. Once the test is completed, the measurement results are calculated and given on the display.

Interrupt / End Test

The test can be interrupted at any time by pressing **STOP**.

FORCED VITAL CAPACITY (FVC) TEST - EXHALATION AND INHALATION

Delete Measurements

If one of the result columns should be deleted, proceed as follows:

Press the number of that column (e.g. for column 1, press key 1) that is to be deleted. If all the results should be deleted, i.e. all three columns, press key **4**.

Screen Information

Once the test is completed, the measurement results are calculated and given on the display. When subsequent tests are made, the result with the highest FVC + FEV_1 value will always be saved and given in the right-hand column (MEAS 1).

The result with the lowest FVC + FEV_1 value of the tests already made and stored will be overwritten. An asterisk ("*") indicates the measurement results of the last test made.

NOTE: The marked results correspond to the displayed test curve.

Toggle Screen Information

Two different screen types can be displayed to achieve more information. To toggle the screen, press either V(t) or F(V).

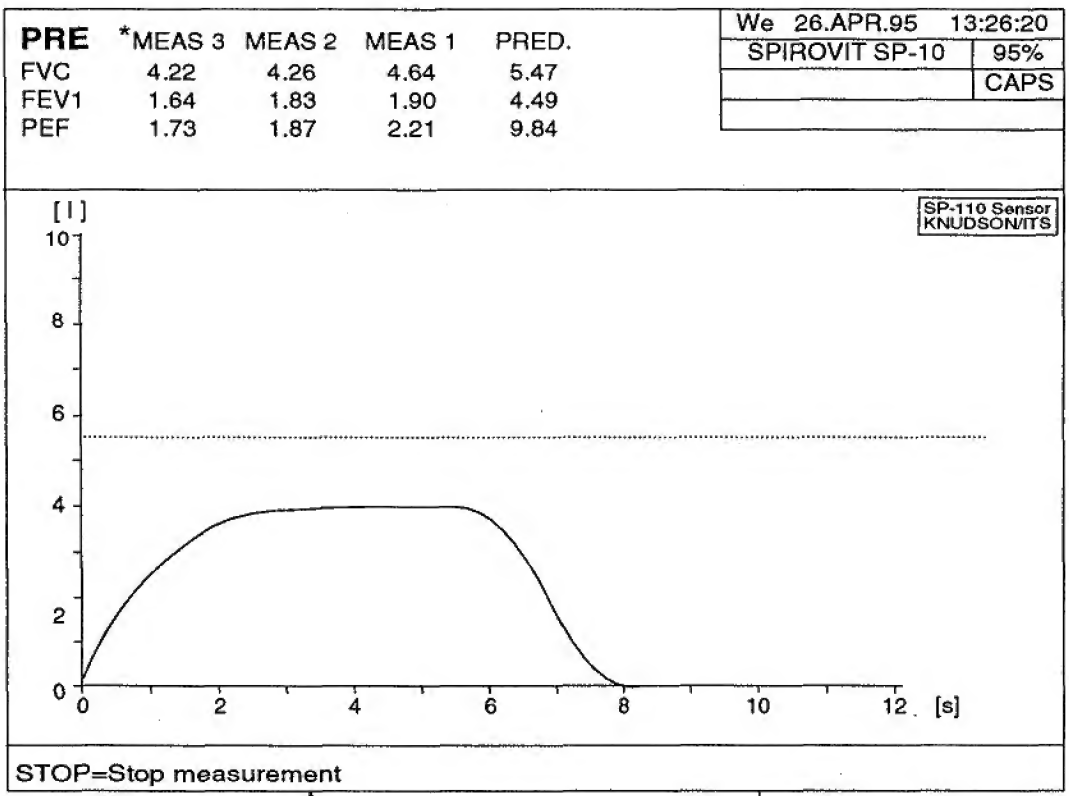
NOTE: The top part of the screen always remains the same.

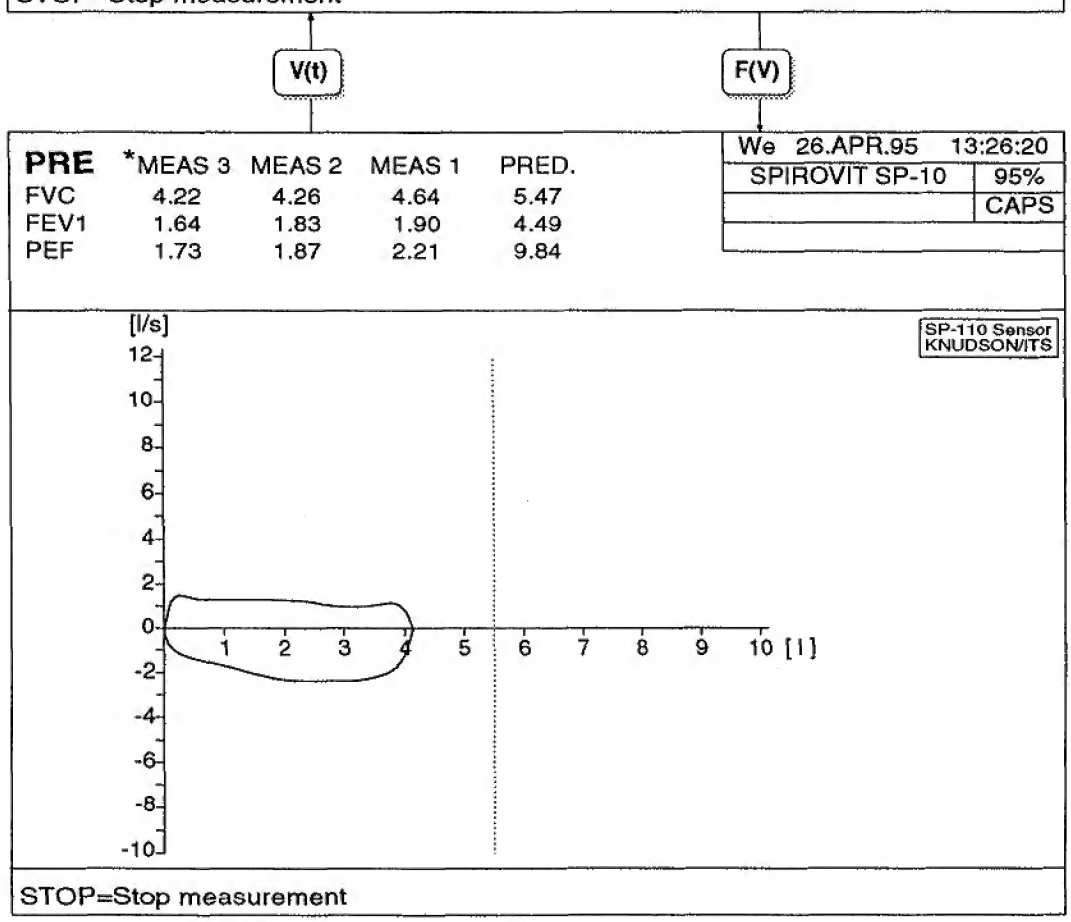
- With V(t) the chart is given as volume (in litres) in relation of time (in seconds).
- With F(V) the chart is given as flow speed (in litres per seconds) in relation to the air volume (in litres).

The information of the previous screen remains stored and can be displayed with the other key as long as no further test was made.

NOTE: These keys only function with the FVC test.

FORCED VITAL CAPACITY (FVC) TEST - EXHALATION AND INHALATION





FORCED VITAL CAPACITY (FVC) TEST - EXHALATION AND INHALATION

Display Results

To display results of the test, press RESULTS and the following information is displayed:

PRE	*MEAS 3	MEAS 2	MEAS 1	PRED.
FVC	4.22	4.26	4.64	5.47
FEV1	1.64	1.83	1.90	4.49
PEF	1.73	1.87	2.21	9.84

We 26.APR.95	13:26:20
SPIROVIT SP-10	95%
	CAPS

		PRED.	MEAS1	MEAS2	MEAS3	%PRED
FVC	[l]	5.47	4.64	4.26	4.22	85
FEV1	[l]	4.49	1.90	1.83	1.64	42
FEV1/FVC	[%]	83.3	41.0	43.1	38.9	49
FEF.2-1.2	[l/s]	8.23	2.02	1.67	1.66	24
FEF25-75%	[l/s]	4.75	1.35	1.65	1.41	28
FEF75-85%	[l/s]	1.40	1.00	1.08	0.94	72
PEF	[l/s]	9.84	2.21	1.87	1.73	22
MEF75%	[l/s]	8.47	1.86	1.84	1.63	22
MEF50%	[l/s]	5.74	1.29	1.74	1.60	22
MEF25%	[l/s]	2.36	1.19	1.20	1.06	50
FMFT	[s]	- - -	1.73	1.29	1.49	- - -
FIVC	[l]	- - -	3.86	4.08	4.40	- - -
FIV1	[l]	- - -	2.72	1.46	1.52	- - -
FIV1/FIVC	[%]	- - -	70.6	35.9	35.5	- - -
FIV1/FVC	[%]	- - -	58.7	34.4	36.0	- - -
PIF	[l/s]	- - -	3.33	1.69	2.12	- - -
MIF50%	[l/s]	- - -	2.99	1.68	2.05	- - -
SVC	[l]	- - -	- - -	- - -	- - -	- - -
ERV	[l]	- - -	- - -	- - -	- - -	- - -
IRV	[l]	- - -	- - -	- - -	- - -	- - -
TV	[l]	- - -	- - -	- - -	- - -	- - -
MVV	[l/min]	150.8	- - -	- - -	- - -	- - -
MV	[l/min]	- - -	- - -	- - -	- - -	- - -

Press FNCT or ESC to exit.

Insert / Edit Diagnosis

Press the RESULTS key when in the results menu once more to insert or edit the diagnosis.

Press FNCT or ESC to exit.

SLOW VITAL CAPACITY (SVC) TEST

For this test the patient should breathe normally 3 times and then inhale maximally to total lung capacity and then expire maximally.

Inform the patient so, that it is sure that he understands what is required of him.

To be able to carry out a Slow Vital Capacity (SVC) test, first press the SVC key.

As soon as the basic screen is displayed, check if all the necessary information is displayed in the top part of the screen according to the requested setup.

Carry Out Test

NOTE: The flow sensor must be held quite still and no air should be breathed into the device for at least one second before and after the START key is pressed.

- Press the green START key to start the test.

The message "READY FOR MEASUREMENT" appears on the display. As soon as the patient starts to breathe into the flow sensor, the unit begins to record the flow and the corresponding curve is represented on the display. An acoustic "beep" indicates when the break-off point for the measurement has been reached.

Five seconds later, the measurement will be automatically interrupted unless the patient carries on. Measurements will still take place should this break-off point not be reached. Once the test is completed, the measurement results are calculated and given on the display.

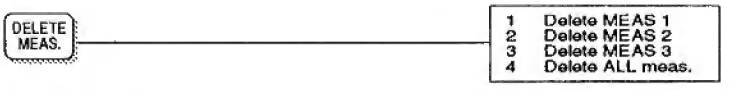
Interrupt / End Test

The test can be interrupted at any time by pressing STOP.

SLOW VITAL CAPACITY (SVC) TEST

Delete Measurements

If one of the result columns should be deleted, proceed as follows:

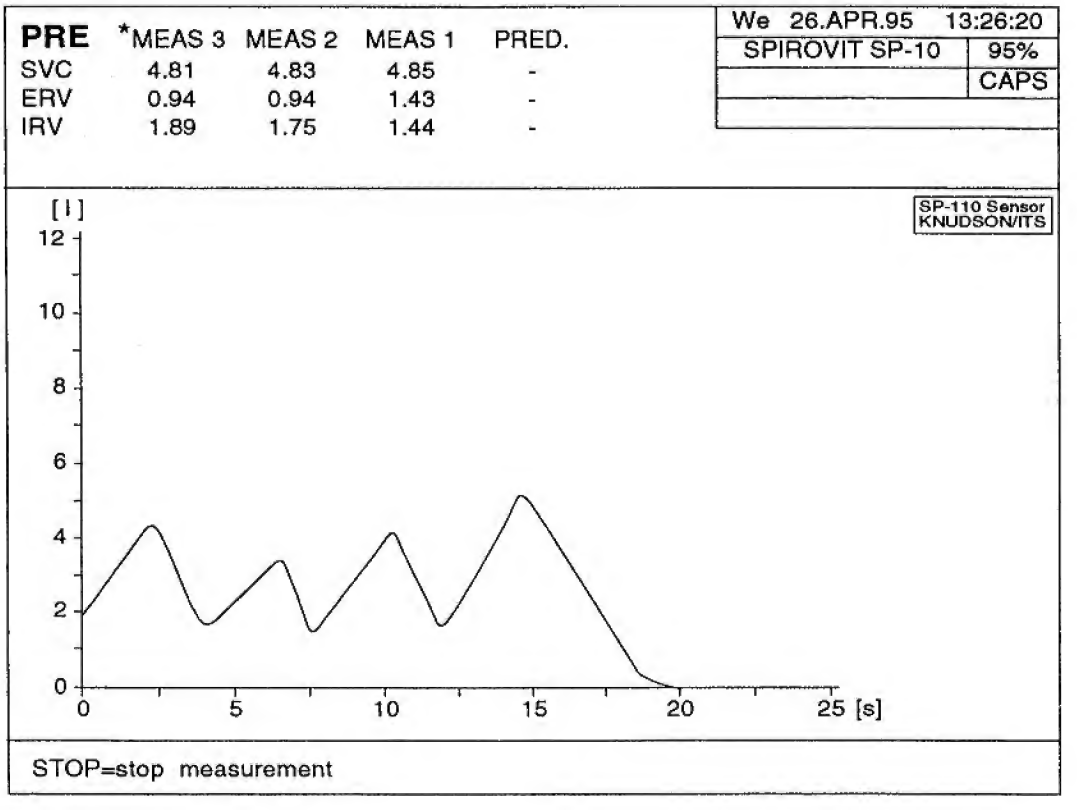


Press the number of that column (e.g. for column 1, press key 1) that is to be deleted. If all the results should be deleted, i.e. all three columns, press key **4.**

Screen Information

When subsequent tests are made, the result with the highest SVC + ERV value will always be saved and given in the right-hand column (MEAS 1). The result with the lowest SVC + ERV value of the tests already made and stored will be overwritten. An asterisk ("*") indicates the measurement results of the last test made.

NOTE: The marked results correspond to the displayed test curve.



SLOW VITAL CAPACITY (SVC) TEST

Display Results

To display results of the test, press RESULTS and the following information is displayed:

PRE

	*MEAS 3	MEAS 2	MEAS 1	PRED.
SVC	4.81	4.83	4.85	-
ERV	0.94	0.94	1.43	-
IRV	1.89	1.75	1.44	-

We 26.APR.95 13:26:20
SPIROVIT SP-10 95%
CAPS

		PRED.	MEAS1	MEAS2	MEAS3	%PRED
FVC	[l]	5.47	4.64	4.26	4.22	85
FEV1	[l]	4.49	1.90	1.83	1.64	42
FEV1/FVC	[%]	83.3	41.0	43.1	38.9	49
FEF.2-1.2	[l/s]	8.23	2.02	1.67	1.66	24
FEF25-75%	[l/s]	4.75	1.35	1.65	1.41	28
FEF75-85%	[l/s]	1.40	1.00	1.08	0.94	72
PEF	[l/s]	9.84	2.21	1.87	1.73	22
MEF75%	[l/s]	8.47	1.86	1.84	1.63	22
MEF50%	[l/s]	5.74	1.29	1.74	1.60	22
MEF25%	[l/s]	2.36	1.19	1.20	1.06	50
FMFT	[s]	- - -	1.73	1.29	1.49	- - -
FIVC	[l]	- - -	3.86	4.08	4.40	- - -
FIV1	[l]	- - -	2.72	1.46	1.52	- - -
FIV1/FIVC	[%]	- - -	70.6	35.9	35.5	- - -
FIV1/FVC	[%]	- - -	58.7	34.4	36.0	- - -
PIF	[l/s]	- - -	3.33	1.69	2.12	- - -
MIF50%	[l/s]	- - -	2.99	1.68	2.05	- - -
SVC	[l]	- - -	4.85	4.83	4.81	- - -
ERV	[l]	- - -	1.43	0.94	0.94	- - -
IRV	[l]	- - -	1.44	1.75	1.89	- - -
TV	[l]	- - -	1.98	2.15	1.97	- - -
MVV	[l/min]	150.8	- - -	- - -	- - -	- - -
MV	[l/min]	- - -	- - -	- - -	- - -	- - -

Press FNCT or ESC to exit.

Insert / Edit Diagnosis

Press the RESULTS key when in the results menu once more to insert or edit the diagnosis.

Press FNCT or ESC to exit.

EXPIRED OR MINUTE VENTILATION (MV) TEST

For this test the patient should breathe as **normally as possible** for up to 60 seconds, but for at least 20 seconds.

Inform the patient so, that it is sure that he understands what is required of him.

To be able to carry out a test for Expired or Minute Ventilation (MV), first press the **MV** key.

As soon as the basic screen is displayed, check if all the necessary information is displayed in the top part of the screen according to the requested setup.

Carry Out Test

NOTE: The flow sensor must be held quite still and no air should be breathed into the device for at least one second before and after the START key is pressed.

- Press the green **START** key to start the test.

The message "READY FOR MEASUREMENT" appears on the display. As soon as the patient starts to breath into the flow sensor, the unit begins to record the flow and the corresponding curve is represented on the display. An acoustic "beep" indicates when the break-off point for the measurement has been reached.

Five seconds later, the measurement will be automatically interrupted unless the patient carries on. Measurements will still take place should this break-off point not be reached. Once the test is completed, the measurement results are calculated and given on the display.

Interrupt / End Test

The test can be interrupted at any time by pressing **STOP**.

Delete Measurements

If one of the result columns should be deleted, proceed as follows:

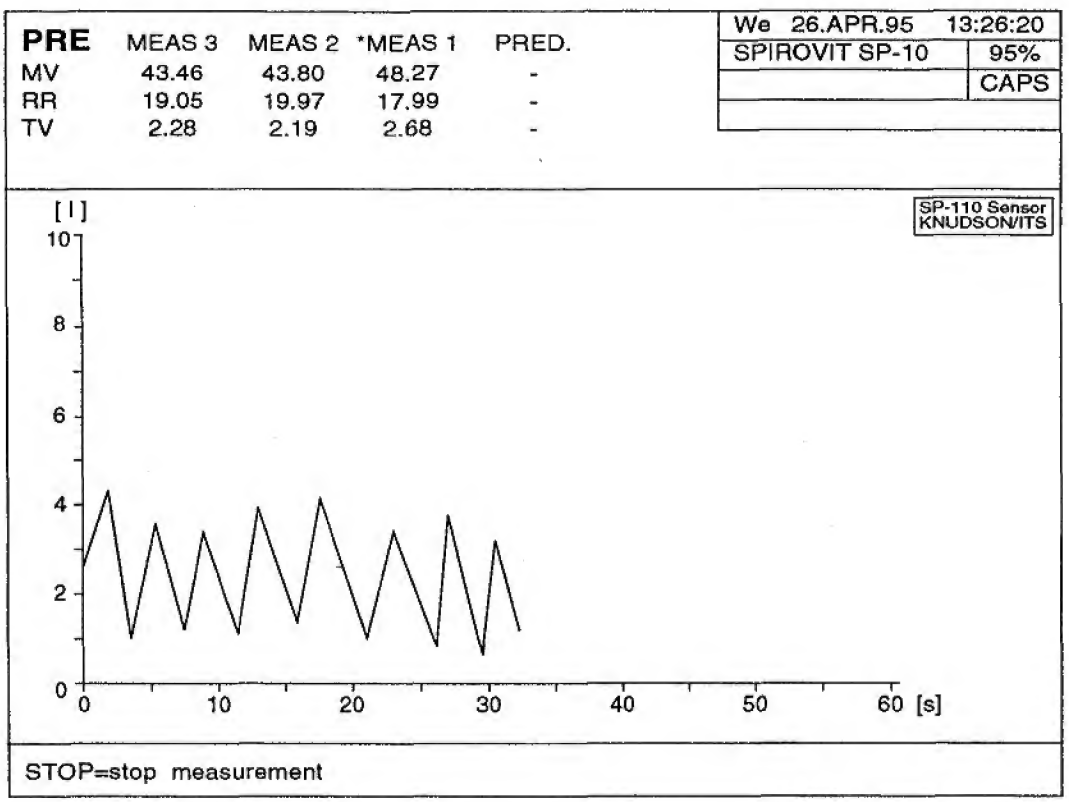
Press the number of that column (e.g. for column 1, press key 1) that is to be deleted. If all the results should be deleted, i.e. all three columns, press key **4**.

EXPIRED OR MINUTE VENTILATION (MV) TEST

Screen Information

When subsequent tests are made, the result with the highest SVC + ERV value will always be saved and given in the right-hand column (MEAS 1). The result with the lowest SVC + ERV value of the tests already made and stored will be overwritten. An asterisk ("*") indicates the measurement results of the last test made.

NOTE: The marked results correspond to the displayed test curve.



EXPIRED OR MINUTE VENTILATION (MV) TEST

Display Results

To display results of the test, press RESULTS and the following information is displayed:

PRE	MEAS 3	MEAS 2	*MEAS 1	PRED.
MV	43.46	43.80	48.27	-
RR	19.05	19.97	17.99	-
TV	2.28	2.19	2.68	-

We 26.APR.95	13:26:20
SPIROVIT SP-10	95%
	CAPS

		PRED.	MEAS1	MEAS2	MEAS3	%PRED
FVC	[l]	5.47	4.64	4.26	4.22	85
FEV1	[l]	4.49	1.90	1.83	1.64	42
FEV1/FVC	[%]	83.3	41.0	43.1	38.9	49
FEF.2-1.2	[l/s]	8.23	2.02	1.67	1.66	24
FEF25-75%	[l/s]	4.75	1.35	1.65	1.41	28
FEF75-85%	[l/s]	1.40	1.00	1.08	0.94	72
PEF	[l/s]	9.84	2.21	1.87	1.73	22
MEF75%	[l/s]	8.47	1.86	1.84	1.63	22
MEF50%	[l/s]	5.74	1.29	1.74	1.60	22
MEF25%	[l/s]	2.36	1.19	1.20	1.06	50
FMFT	[s]	---	1.73	1.29	1.49	---
FIVC	[l]	---	3.86	4.08	4.40	---
FIV1	[l]	---	2.72	1.46	1.52	---
FIV1/FIVC	[%]	---	70.6	35.9	35.5	---
FIV1/FVC	[%]	---	58.7	34.4	36.0	---
PIF	[l/s]	---	3.33	1.69	2.12	---
MIF50%	[l/s]	---	2.99	1.68	2.05	---
SVC	[l]	---	4.85	4.83	4.81	---
ERV	[l]	---	1.43	0.94	0.94	---
IRV	[l]	---	1.44	1.75	1.89	---
TV	[l]	---	1.98	2.15	1.97	---
MVV	[l/min]	150.8	---	---	---	---
MV	[l/min]	---	48.3	43.8	43.5	---

Press FNCT or ESC to exit.

Insert / Edit Diagnosis

Press the RESULTS key when in the results menu once more to insert or edit the diagnosis.

Press FNCT or ESC to exit.

MAXIMUM VOLUNTARY VENTILATION (MVV) TEST

For this test the patient should breathe as deeply and as rapidly as possible over a period of 6 to 12 seconds.

Inform the patient so, that it is sure that he understands what is required of him.

WARNING:

EXTREME CARE SHOULD BE EXERCISED WHEN PERFORMING THIS TEST AS THERE IS A DANGER OF HYPERVENTILATION.

To be able to carry out a test for Maximum Voluntary Ventilation (MVV), first press the **MVV** key.

As soon as the basic screen is displayed, check if all the necessary information is displayed in the top part of the screen according to the requested setup.

Carry Out Test

NOTE: The flow sensor must be held quite still and no air should be breathed into the device for at least one second before and after the START key is pressed.

- Press the green **START** key to start the test.

The message "READY FOR MEASUREMENT" appears on the display. As soon as the patient starts to breathe into the flow sensor, the unit begins to record the flow and the corresponding curve is represented on the display. An acoustic "beep" indicates when the break-off point for the measurement has been reached.

Five seconds later, the measurement will be automatically interrupted unless the patient carries on. Measurements will still take place should this break-off point not be reached. Once the test is completed, the measurement results are calculated and given on the display.

When subsequent tests are made, the result with the highest MVV value will always be saved and given in the right-hand column (MEAS 1). The result with the lowest MVV value of the tests already made and stored will be overwritten. An asterisk ("*") indicates the measurement results of the last test made.

Interrupt / End Test

The test can be interrupted at any time by pressing **STOP**.

MAXIMUM VOLUNTARY VENTILATION (MVV) TEST

Delete Measurements

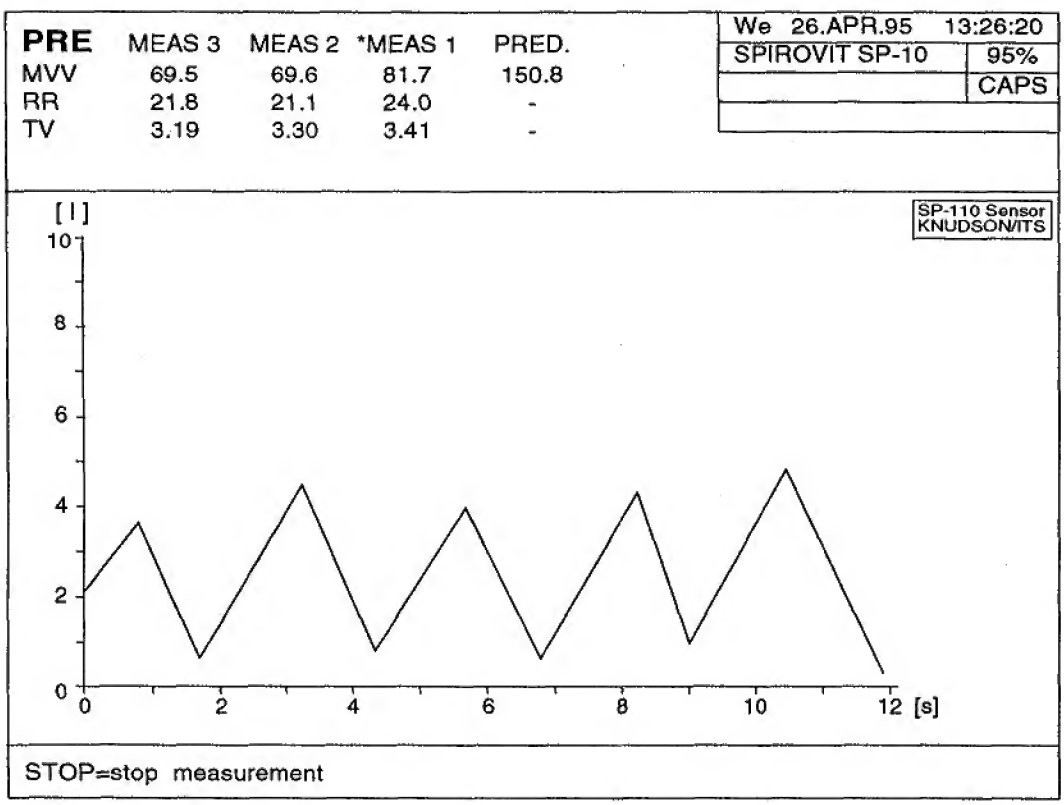
If one of the result columns should be deleted, proceed as follows:

Press the number of that column (e.g. for column 1, press key 1) that is to be deleted. If all the results should be deleted, i.e. all three columns, press key **4**.

Screen Information

When subsequent tests are made, the result with the highest SVC + ERV value will always be saved and given in the right-hand column (MEAS 1). The result with the lowest SVC + ERV value of the tests already made and stored will be overwritten. An asterisk ("*") indicates the measurement results of the last test made.

NOTE: The marked results correspond to the displayed test curve.



MAXIMUM VOLUNTARY VENTILATION (MVV) TEST

Display Results

To display results of the test, press RESULTS and the following information is displayed:

PRE	MEAS 3	MEAS 2	*MEAS 1	PRED.
MVV	69.5	69.6	81.7	150.8
RR	21.8	21.1	24.0	-
TV	3.19	3.30	3.41	-

We 26.APR.95 13:26:20
SPIROVIT SP-10 | 95%
CAPS

		PRED.	MEAS1	MEAS2	MEAS3	%PRED
FVC	[l]	5.47	4.64	4.26	4.22	85
FEV1	[l]	4.49	1.90	1.83	1.64	42
FEV1/FVC	[%]	83.3	41.0	43.1	38.9	49
FEF.2-1.2	[l/s]	8.23	2.02	1.67	1.66	24
FEF25-75%	[l/s]	4.75	1.35	1.65	1.41	28
FEF75-85%	[l/s]	1.40	1.00	1.08	0.94	72
PEF	[l/s]	9.84	2.21	1.87	1.73	22
MEF75%	[l/s]	8.47	1.86	1.84	1.63	22
MEF50%	[l/s]	5.74	1.29	1.74	1.60	22
MEF25%	[l/s]	2.36	1.19	1.20	1.06	50
FMFT	[s]	- - -	1.73	1.29	1.49	- - -
FIVC	[l]	- - -	3.86	4.08	4.40	- - -
FIV1	[l]	- - -	2.72	1.46	1.52	- - -
FIV1/FIVC	[%]	- - -	70.6	35.9	35.5	- - -
FIV1/FVC	[%]	- - -	58.7	34.4	36.0	- - -
PIF	[l/s]	- - -	3.33	1.69	2.12	- - -
MIF50%	[l/s]	- - -	2.99	1.68	2.05	- - -
SVC	[l]	- - -	4.85	4.83	4.81	- - -
ERV	[l]	- - -	1.43	0.94	0.94	- - -
IRV	[l]	- - -	1.44	1.75	1.89	- - -
TV	[l]	- - -	1.98	2.15	1.97	- - -
MVV	[l/min]	150.8	81.7	69.6	69.5	54
MV	[l/min]	- - -	48.3	43.8	43.5	- - -

Press FNCT or ESC to exit.

Insert / Edit Diagnosis

Press the RESULTS key when in the results menu once more to insert or edit the diagnosis.

Press FNCT or ESC to exit.

POST-MEDICATION TESTS

Each time the Pulmonary Function Testing program is called up, the unit assumes that premeditation tests are to be carried out. This is confirmed by "PRE" which appears in the top left-hand corner of the screen.

The post-medication function is selectable for the following tests:

- FVC Test
- SVC Test
- MV Test
- MVV Test

Select Post-Medication

In order to carry out post-medication tests for comparison, simply press **PRE/POST** and "POST" appears in the top left-hand corner as in the following example:

POST MEAS 3	MEAS 2	MEAS 1	PRED.
FVC			5.47
FEV1			4.49
PEF			9.84

NOTE The post-medication tests are carried out in the same way as the premeditation tests.

Print Post-Medication Tests

The printout following post-medication tests will give the curves of both pre and post-medication tests (the premedication curve is bold).

The measurement results are shown as the actual results, actual results as a percentage of those predicted, and the percentage change (i.e. difference) from pre to post-medication results.

NOTE: The premedication results used for the comparison printout are those with the highest values, and not necessarily the last taken.

The diagnosis resulting from the premedication test is also given on this printout.

PRINTING TEST CURVES AND RESULTS

By pressing either PRINT BEST, PRINT ALL or PRINT SEL., a printout is made according to the selection:

- With PRINT BEST the best result is printed.
- With PRINT ALL all results are printed.
- With PRINT SEL. only selected results are printed.

The patient data, the time and date and the standard used for calculation are printed out for every test but the type of curve and test results will depend on the type of test.

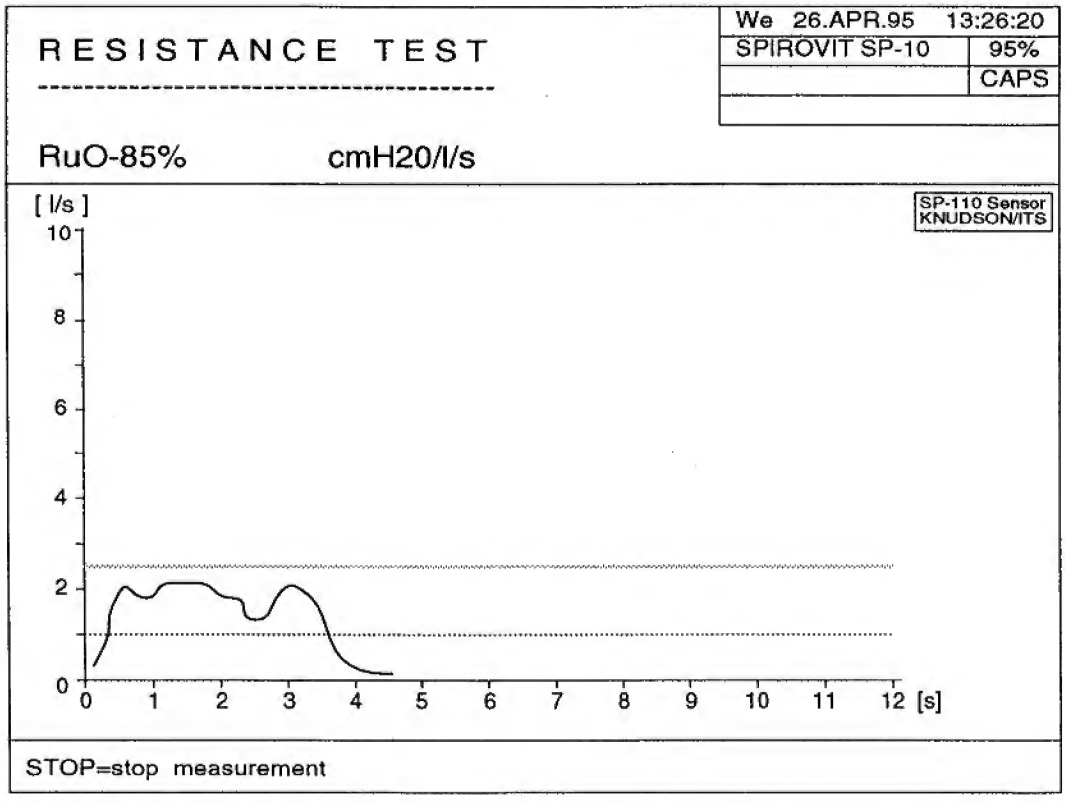
A printout can be interrupted at any time by pressing STOP.

RESISTANCE TEST OPTION

Resistance measurement enables the early detection of an obstruction in the respiratory tract through measurement of the lung pressure necessary for exhalation.

Test Procedure

To call up the expiration resistance test, press **RESIS.** and the corresponding coordinates appear as in the following example:



The display indicates that an average resistance value will be measured between 0 and 85% of the expired volume of air. To the right, the actual measured resistance will be given as a pressure value in cm H_2O / litre / second. The coordinates represent the graph on which the curve will be drawn with the expiratory flow on the vertical axis and the time in seconds on the horizontal axis.

The patient should inhale as deeply as possible before starting the test and then exhale through the flow sensor in such a way that the curve on the display remains between the two horizontal markers (i.e. between 1 and 2.5 litres). This may require several trial runs before the patient achieves the necessary flow of exhaled air so make sure that he is aware of this and that he understands what is required of him.

NOTE: At regular intervals during exhalation, the air flow will be interrupted for very short periods. If the air flow is too strong (>2.5 l/s) then the shutter could become blocked and the measurement will be invalid.

RESISTANCE TEST OPTION

Print Resistance Tests

- PRINT BEST, PRINT SEL. or PRINT ALL gives the following:

- Patent data
- Norm values
- Diagnosis (as indication) (if selected under "Settings")
- Resistance curve as shown on the display.
- Measured pressure as cmH_2O / litres / second.

Where a VC test has also been carried out, the ERV and EV values appear together with the resistance value of the expired volume at ERV.

CHAPTER 3

Diagnosis and Norm Values

Explanation of Measured Values

FVC	**Forced vital capacity expiration** volume achieved by the quickest possible exhalation after a maximal inhalation.
$FEV_{0.5/1.0/3.0}$	**Forced expiratory volume lung** volume in litres, measured after 0.5, 1.0 or 3 seconds forced expiration.
FEF	**Forced Expiratory Flow respiratory** flow in terms of differing lung volumes measured in litres per second.
$FEF_{25-75\%}$	flow speed of the expired air by 25 to 75% of the forced vital capacity (FVC)
$FEF_{75-85\%}$	flow speed of the expired air by 75 to 85% of the forced vital capacity (FVC)
$FEF_{25\%}$	flow speed of the expired air by 25% of the forced vital capacity (FVC)
$FEF_{50\%}$	flow speed of the expired air by 50% of the forced vital capacity (FVC)
$FEF_{75\%}$	flow speed of the expired air by 75% of the forced vital capacity (FVC)
$FEF_{.2-1.2}$	averaged flow between 0.2 and 1.2 litres of the forced expired vital capacity
PEF	**Peak Expiratory Flow**
MEF	**Maximum Expiratory Flow**
$MEF_{75\%}$	flow speed of the expired air by 25% of the forced vital capacity (FVC)
$MEF_{50\%}$	flow speed of the expired air by 50% of the forced vital capacity (FVC)
$MEF_{25\%}$	flow speed of the expired air by 75% of the forced vital capacity (FVC)
$MEF_{75\%} = FEF_{25\%}$	
$MEF_{50\%} = FEF_{50\%}$	
$MEF_{25\%} = FEF_{75\%}$	
ERV	**Expiratory Reserve Volume possible** further expiration starting from the normal expiration level
IRV	**Inspiratory Reserve Volume possible** further inspiration starting from the normal inspiration level
TV	**Tidal Volume expirational** and inspirational volumes during normal respiration
SVC	**Slow Vital Capacity lung** volume measured from a complete expiration following a deep inspiration
MV	**Expired or Minute Ventilation volume** of expired air in litres per minute measured over a minimum of one minute

Explanation of Measured Values

MVV	**Maximum Voluntary Ventilation maximum** volume of air which can be moved on expiration while breathing as deeply and as rapidly as possible
RR	**Respiration Rate**
FMFT	**Forced Mid-expiratory Flow Time time** difference between the 25% and 75% points of the FVC
FIVC	**Forced Inspiratory Vital Capacity inspiration** volume achieved between a maximal expiration and a maximal inspiration
$FIV_{1.0}$	forced inspiratory air volume in litres measured in the first second
$FIV_{1.0}$ / FIVC	forced inspiratory air volume measured in the first second as a percentage of forced inspiratory vital capacity
$FIV_{1.0}$ / FVC	forced inspiratory air volume measured in the first second as a percentage of forced expiratory vital capacity
PIF	**Peak Inspiratory Flow maximum** inspiratory flow speed in litres / second
MIF	**Maximum Inspiratory Flow maximum** inspiratory flow in litres
$MIF_{50\%}$	flow speed by 50 % of the forced inspiratory vital capacity

Diagnosis

The diagnostic interpretation is dependent upon the country.

The factors used in the evaluation for diagnosis are automatically included in the respective language software and described in the following chapters.

Diagnosis for Countries Outside the USA

Possible respiratory problems are diagnosed on evaluation of the following factors:

Diagnosis	SVC	FEV1
Normal Condition	>80%	>70%
Restrictive	<80%	-
Obstructive	-	<70%
Combined	<80%	<70%

Restrictive Ventilatory Defect is indicated if $\frac{\text{SVC (or FVC)}}{\text{predicted SVC}}$ x 100% is smaller than 80%.

Obstructive Ventilatory Defect is indicated if $\frac{\text{FEV1}}{\text{SVC}}$ x 100% is smaller than 70%.

If both conditions are satisfied, a Combined Obstructive/Restrictive Ventilatory Defect is indicated.

Diagnosis for USA and Canada

For the USA and Canada, diagnosis of possible respiratory problems is based on the ITS interpretation standard which uses the LLN (Lower Limits of Normal) calculations. These calculations apply to patients between the ages of 5 and 85. The LLN FEV1% value is calculated as follows:

	Male		Female	
Adult	>26 yrs:	Predicted FEV1% -9.2	>21 yrs:	Predicted FEV1% -11.1
Adolescent	19 to 25 yrs:	Predicted FEV1% x 0.848	19 to 20 yrs:	Predicted FEV1% x 0.805
Child	<18 yrs:	Predicted FEV1% x 0.826	<18 yrs:	Predicted FEV1% x 0.791

Using this LLN value, the diagnostic statements and their criteria are as follows:

Diagnosis	Criteria
Normal limits	%FEVpredicted is >80%
Borderline Obstruction	FEV1 is 80 to 100% of LLN
Mild Obstruction	FEV1 is 60 to 80% of LLN
Moderate Obstruction	FEV1 is 40 to 60% of LLN
Severe Obstruction	FEV1 is <40% of LLN
Mild Restriction	%FVCpredicted is 60 to 80%
Moderate Restriction	%FVCpredicted is 50 to 60%
Severe Restriction	%FVCpredicted is <50%

Norm Values

The norm values used for the calculation of predicted values are dependent upon the country.

- For Great Britain, Italy, Spain and Switzerland, the ECCS and Quanjer standards are used.
- For Sweden, the Swedish (Berglund) and Quanjer standards are used.
- In Finland the Finnish and Quanjer standards are used.
- In Austria the Austrian standards are used.
- In India the Indian norm values are used.
- In America and Canada the norm values that are used are Knudson, Knudson76, Crapo, Morris, Composite and Polgar. The American norm values are extended with values taken from the ITS (Intermountain Thoracic Society) recommendations.

The factors used in the evaluation for diagnosis and the specific norm values are included in the software and are described in the following pages.

IMPORTANT:

DUE TO GREAT DIFFERENCES IN THE SIZE OF THE LUNGS OF CHILDREN, THERE ARE NO STANDARD VALUES FOR CHILDREN UNDER 6 YEARS OF AGE.

Norm Values for Countries Outside the USA

ECCS Values

The safety standards of the European Coal and Steel Community Standards (ECCS) are valid for adults of at least 25 years of age. Patients between the ages of 18 and 25 are calculated on the basis of a 25 year old. The calculation equations are as follows:

	Males	Females
SVC	6.103 x H -0.028 x A -4.654	4.664 x H -0.024 x A -3.284
FVC	5.757 x H -0.026 x A -4.345	4.426 x H -0.026 x A -2.887
FEV1	4.301 x H -0.029 x A -2.492	3.953 x H -0.025 x A -2.604
FEV1/SVC	-0.179 x A +87.21	-0.192 x A +89.10
MEF	1.944 x H -0.043 x A +2.699	1.252 x H -0.034 x A +2.924
PEF	6.146 x H -0.043 x A +0.154	5.50 x H -0.030 x A -1.106
MEF75	5.459 x H -0.029 x A -0.470	3.218 x H -0.025 x A +1.596
MEF50	3.794 x H -0.031 x A -0.352	2.450 x H -0.025 x A +1.156

H: Height in meters

A: Age

Norm Values

Quanjer & Tammeling Comparisons

The Quanjer and Tammeling comparison is valid for children between the ages of 6 and 17 as follows:

	Boys	Girls
SVC = FVC	1.00 x H(power 2.7)	0.95 x H(power 2.7)
FEV1	0.84 x H(power 2.7)	0.81 x H(power 2.7)
FEV1/SVC	0.84	0.84
MEF = PEF	8.2 x H -6.8	6.6 x H -5.3
MEF50	5.6 x H -4.4	4.6 x H -3.3

H: Height in meters

Austrian Standard Values (Österreich)

The Austrian standard values are valid for children between the ages of 7 and 18 and adults between the ages of 19 and 70 are as follows:

BOYS 5 - 17.99 years (1.09 - 1.96m)
ln(FVC) = -1.142 + 1.259H + 0.004070A √W
ln(FEV1) = -1.178 + 1.221H + 0.003841A √W
ln(PEF) = -0.214 + 0.921H + 0.0467A + 0.0020W
ln(PEF75) = -0.077 + 0.770H + 0.0373A + 0.0025W
ln(PEF50) = -0.522 + 0.843H + 0.0300A + 0.0035W
ln(PEF25) = -1.576 + 1.166H + 0.0219A + 0.0021W
FEV1 %FVC = 101.99 - 1.191H(power 2) - 3.962ln(A)
GIRLS 5 - 15.99 years (1.10 - 1.82m)
ln(FVC) = -3.842 + 4.1632√H + 0.1341√A - 1.614Fi
ln(FEV1) = -3.877 + 3.9809√H + 0.1485√A - 1.322Fi
ln(PEF) = 0.411 + 1.793ln(H) + 0.4251ln(A) - 0.910Fi
ln(MEF75) = 0.455 + 1.616ln(H) + 0.3738ln(A) - 0.861Fi
ln(MEF50) = 0.256 + 1.643ln(H) + 0.3481ln(A) - 1.089Fi
ln(MEF25) = -0.772 + 2.002ln(H) + 0.3063ln(A) - 0.409Fi
FEV1 %FVC = Mw = 92.33
MALES 18 - 90 years (1.44 - 2.00m)
FVC = -11.606 + 8.172H - 0.0339A x H + 1.2869ln(A)
FVC1 = -8.125 + 6.212H - 0.0300A x H + 0.9770ln(A)
√PEF = 1.798 + 2.311ln(H) + 0.0159A - 0.000248A(power 2)
√PEF75 = 1.581 + 1.854ln(H) + 0.0213A - 0.000283A(power 2)
√PEF50 = 1.490 + 1.290ln(H) + 0.0125A - 0.000218A(power 2)
√PEF25 = 1.314 + 0.898ln(H) - 0.0083A - 0.000026A(power 2)
FEV1 %FVC = 101.99 - 1.191H(power 2) - 3.962ln(A)
FEMALES 16 - 90 years (1.40 - 1.90m)
FVC = -10.815 + 6.640H - 0.0408A x H + 1.7293ln(A)
FVC1 = -6.995 + 5.174H - 0.0314A x H + 1.0251ln(A)
√PEF = 1.832 + 1.838ln(H) + 0.0078A - 0.000172A(power 2)
√PEF75 = 1.779 + 1.421ln(H) + 0.0096A - 0.000179A(power 2)
√PEF50 = 1.561 + 1.177ln(H) + 0.0045A - 0.000140A(power 2)
√PEF25 = 1.372 + 0.938ln(H) - 0.0152A + 0.000036A(power 2)
FEV1 %FVC = 118.993 - 3.0320H(power 2) - 6.9053ln(A)

H = Height in meters A = Age in years

W = weight in kg Fi = body fat index = $H/\sqrt[3]{W}$

Norm Values

Swedish Standards (Berglund)

The Swedish (Berglund) standard is valid for adults between the ages of 18 and 75 years as follows:

	Males	Females
FEV%	91.79 -(0.373 x A)	92.11 -(0.261 x A)
SVC	1.09 [(4.81 x H) -(0.020 x A) -2.81]	1.09 [(4.04 x H) -(0.022 x A) -2.35]
FEV	1.01.09 [(3.44 x H) -(0.033 x A) -1.00]	1.09 [(2.67 x H) -(0.027 x A) -0.54]

A: Age

H: Height in meters

Finnish Standards

The Finnish standard is valid for adults from the age of 18 years as follows:

Males	
SVC (l)	exp [(-0.00833 x A) + (0.6309 x log A) + (-1.4750 / H) + 0.9047]
FEV1 (l)	exp [(-0.00587 x A) + (0.2756 x log A) + (-1.1655 / H) + 1.0980]
FVC (l)	exp [(-0.00827 x A) + (0.5860 x log A) + (-1.4468 / H) + 0.9461]
FEV1 / SVC (%)	exp [(0.00246 x A) + (-0.3553 x log A) + (0.3095 / H) + 2.1933]
FEV1 / FVC (%)	exp [(0.00240 x A) + (-0.3104 x log A) + (0.2813 / H) + 2.1519]
PEF (l/s)	exp [(-0.00211 x A) + (0.1049 x log A) + (-0.6774 / H) + 1.3255]
Females	
SVC (l)	exp [(-0.01016 x A) + (0.6995 x log A) + (-1.4518 / H) + 0.7763]
FEV1 (l)	exp [(-0.00920 x A) + (0.4772 x log A) + (-1.3284 / H) + 0.9296]
FVC (l)	exp [(-0.00982 x A) + (0.6358 x log A) + (-1.4137 / H) + 0.8320]
FEV1 / SVC (%)	exp [(0.00096 x A) + (-0.2223 x log A) + (0.1233 / H) + 2.1533]
FEV1 / FVC (%)	exp [(0.00062 x A) + (-0.1586 x log A) + (0.0853 / H) + 2.0975]
PEF (l/s)	exp [(-0.00677 x A) + (0.4017 x log A) + (-0.7422 / H) + 0.9661]

A: Age

H: Height in meters

log: Logarithm to base 10

Norm Values

Indian Equations

The Indian equations are valid for patients from the age of 7 years as follows:

	Males	Females
	<30 years old:	
FVC	0.055 x H + 0.019 x A -6.058	0.030 x H + 0.006 x A - 2.284
FEV1	0.039 x H - 0.010 x A -3.266	0.025 x H - 0.011 x A - 1.424
	>30 years old:	
FVC	0.054 x H - 0.018 x A -4.832	0.043 x H - 0.010 x A - 3.755
FEV1	0.037 x H - 0.022 x A -2.650	0.032 x H - 0.012 x A - 2.580
FEV1/FVC	-0.1756 x H - 0.2457 x A -119.346	-0.0334 x H - 0.2146 x A - 94.8867
SVC	0.0522 x H - 0.0114 x A -4.859	0.0587 x H - 0.0296 x A - 5.927
FEV3	0.0485 x H - 0.0183 x A -4.138	0.0533 x H - 0.0105 x A - 5.660
FEF25-75%	0.0173 x H - 0.0407 x A -1.6108	0.0245 x H - 0.0336 x A - 0.1399
PEF	0.0850 x H - 0.0187 x A -6.2083	0.0497 x H - 0.0018 x A - 2.7154
FEF50	0.0195 x H - 0.0365 x A -1.7383	0.0272 x H - 0.0279 x A - 0.2704
FEF75	0.0088 x H - 0.0301 x A -1.0402	0.0113 x H - 0.0288 x A - 0.5012
MVV	1.3056 x H - 0.5228 x A -93.2102	0.7149 x H - 0.3624 x A - 25.0208

A: Age

H: Height in meters

Norm Values for USA and Canada

Morris Norm Values

The Morris equations are valid for women between 56 and 72 inches tall and within the age range of 20 to 90 years, and for men between 58 and 80 inches tall and within the age range of 20 to 90 years as follows:

	Males	Females
FVC		
FEV1	0.0920 x H -0.0320 x A -1.260	0.0890 x H -0.0250 x A -1.932
FEV1/FVC	-0.3118 x H -0.2422 x A +107.120	-0.0679 x H -0.1815 xA +88.700
FEF0.2 - 1.2	0.1090 x H -0.0470 x A +2.010	0.1450 x H -0.0360 x A -2.532
FEF25 - 75	0.0470 x H -0.0450 x A +2.513	0.0600 x H -0.0300 x A +0.551
FEF75 - 85	0.0130 x H -0.0230 x A +1.210	0.0250 x H -0.0210 x A +0.321

The Morris normals are extended with the following:

	Males	Females
FEV0.5	0.0831 x H -0.0152 x A -1.914	0.0605 x H -0.0185 x A -0.809
FEV3.0	-0.1359 x H -0.0271 x A -3.512	-0.1123 x H -0.0257 x A -2.745
FEV3.0/FVC	-0.1593 x H -0.1450 x A +112.090	-0.2380 x H -0.1630 x A +118.160
MVV	3.4040 x H -1.2600 x A -21.400	2.0500 x H -0.5700 x A -5.500

A: Age

H: Height in inches

Norm Values

Crapo Norm Values

The Crapo equations are valid for men between 61 and 77 inches tall and within the age range of 18 to 89 years, and for women between 57 and 71 inches tall and within the age range of 18 to 89 years as follows:

	Males	Females
FVC	0.1524 x H -0.0214 x A -4.650	0.1247 x H -0.0216 x A -3.590
FEV1	0.1052 x H -0.0244 x A -2.190	0.0869 x H -0.0255 x A -1.578
FEV3	0.1359 x H -0.0271 x A -3.512	0.1123 x H -0.0257 x A -2.745
FEV1/FVC	-0.3302 x H -0.1520 x A +110.490	-0.5131 x H -0.2520 xA +126.580
FEF25 - 75	0.0518 x H -0.0380 x A +2.133	0.0391 x H -0.0460 x A +2.683
MVV Vol.	3.4040 x H -1.2600 x A -21.400	2.0500 x H -0.5700 x A -5.500

The Crapo normals are extended with the following ITS equations:

	Males	Females
FEV0.5	0.0831 x H -0.0152 x A -1.914	0.0605 x H -0.0185 x A -0.809
FEV3.0/FVC	-0.1593 x H -0.1450 x A +112.090	-0.2380 x H -0.1630 x A +118.160

A: Age

H: Height in inches

Norm Values

Knudson Norm Values

The Knudson equations are valid for both children and adults in specific groups according to age and height as follows:

	Males	Females
	H = 44 to 61 inches, A = 6 to 11 yrs	*H = 42 to 58 inches, A = 6 to 10 yrs*
FVC	0.1039 x H + 0.0 x A -3.376	0.1092 x H + 0.0 x A -3.749
FVC0.5	0.0760 x H +0.0430 x A -3.050	0.0480 x H + 0.0610 x A -1.740
FEV1	0.0884 x H + 0.0 x A - 2.814	0.0853 x H + 0.0 x A - 2.758
FEV1/FVC	-0.2065 x H + 0.0 x A + 100.439	-0.4849 x H + 0.6655 x A + 109.974
FEF25 - 75	0.0859 x H + 0.0 x A - 2.320	0.0559 x H + 0.0 x A - 0.812
PEF	0.1980 x H + 0.1660 x A - 8.061	0.1240 x H + 0.1570 x A - 3.920
FEF50	0.0960 x H + 0.0 x A - 2.545	0.0 x H + 0.1846 x A + 0.736
FEF75	0.0434 x H + 0.0 x A - 1.015	0.0277 x H + 0.0 x A - 0.166
MVV	4. 6800 x H + 1.8 x A - 192.320	2.7600 x H + 3.4000 x A - 108.120
	H = 55 to 76 inches, A = 12 to 25 yrs	*H = 52 to 72 inches, A = 11 to 20 yrs*
FVC	0.1499 x H + 0.0739 x A - 6.887	0.1057 x H + 0.0699 x A - 4.447
FVC0.5	0.0760 x H + 0.0430 x A - 3.050	0.0480 x H + 0.0610 x A - 1.740
FEV1	0.1318 x H + 0.0636 x A - 6.118	0.0892 x H + 0.0694 x A - 3.762
FEV1/FVC	-0.2065 x H + 0.0 x A + 100.439	-0.4849 x H + 0.6655 x A + 109.974
FEF25 - 75	0.1369 x H + 0.0749 x A - 6.199	0.0709 x H + 0.1275 x A - 2.801
PEF	0.1980 x H + 0.1660 x A - 8.061	0.1240 x H + 0.1570 x A - 3.920
FEF50	0.1379 x H + 0.1150 x A - 6.385	0.0732 x H + 0.1111 x A - 2.304
FEF75	0.1008 x H - 0.0057 x A - 4.242	
MVV	4.6800 x H + 1.8000 x A - 192.320	2.7600 x H + 3.4000 x A - 108.12
FEV3.0	0.1359 x H - 0.0271 x A - 3.512	0.1123 x H - 0.0257 x A - 2.745
FEV3.0/FVC	-0.1593 x H - 0.1450 x A + 112.090	-0.2380 x H - 0.1630 x A + 118.160
	H = 62 to 77 inches, A = 26 to 120 yrs	*H = 58 to 71 inches, A = 21 to 120 yrs*
FVC	0.1524 x H - 0.0214 x A - 4.650	0.1247 x H - 0.0216 x A - 3.590
FVC0.5	0.0831 x H - 0.0152 x A - 1.914	0.0605 x H - 0.0185 x A - 0.809
FEV1	0.1052 x H - 0.0244 x A - 2.190	0.0869 x H - 0.0255 x A - 1.578
FEV3.0	0.1359 x H - 0.0271 x A - 3.512	0.1067 x H - 0.0257 x A - 2.745
FEV1/FVC	0.0 x H - 0.1050 x A + 86.686	-0.4704 x H - 0.1896 x A + 121.678
FEF25 - 75	0.1471 x H - 0.0363 x A - 4.518	0.0531 x H - 0.0344 x A + 1.128
FEF75 - 85	0.0130 x H - 0.0230 x A + 1.210	0.0250 x H - 0.0210 x A + 0.321
PEF	0.2390 x H - 0.0350 x A - 5.990	0.1240 x H - 0.0250 x A - 0.740
FEF25	0.0900 x H - 0.0200 x A + 2.726	0.0690 x H - 0.0190 x A + 2.147
FEF50	0.1737 x H - 0.0366 x A - 5.409	0.0681 x H - 0.0289 x A + 0.609
FEF75	0.0787 x H - 0.0230 x A - 2.483	0.0244 x H - 0.0259 x A + 1.118
MVV	3.0300 x H - 0.8160 x A - 37.900	2.1400 x H - 0.6850 x A - 4.870
FEV3.0/FVC	-0.1593 x H - 0.1450 x A + 112.090	-0.2380 x H - 0.1630 x A + 118.160

A: Age

H: Height in inches

Norm Values

Knudson 76 Norm Values

The Knudson 76 equations are valid for both males and females in specific age groups as follows:

	Males	Females
	Age <25 yrs	*Age <20 yrs*
FVC	0.1270 x H + 0.078 x A -5.508	0.0838 x H + 0.092 x A -3.469
FVC0.5	0.0762 x H +0.043 x A -3.054	0.0483 x H + 0.061 x A -1.738
FEV1.0	0.1168 x H + 0.045 x A - 4.808	0.0686 x H + 0.085 x A - 2.703
FEV3.0	0.1321 x H + 0.066 x A - 5.531	0.0838 x H + 0.086 x A - 3.417
FEV1/FVC	-0.2210 x H - 0.140 x A + 103.64	-0.2819 x H - 0.109 x A + 107.38
FEF25 - 75	0.1499 x H + 0.0 x A - 5.443	0.0635 x H + 0.121 x A - 0.893
PEF	0.1981 x H + 0.166 x A - 8.060	0.1245 x H + 0.157 x A - 3.916
FEF25	0.1778 x H + 0.147 x A - 7.054	0.1118 x H + 0.144 x A - 3.365
FEF50	0.1295 x H + 0.081 x A - 4.975	0.0864 x H + 0.120 x A - 2.531
FEF75	0.0813 x H + 0.0 x A - 2.455	0.0 x H + 0.139 x A + 0.692
	Age ≥25 yrs	*Age ≥20 yrs*
FVC	0.1651 x H - 0.029 x A - 5.459	0.0940 x H - 0.022 x A - 1.774
FVC0.5	0.0940 x H - 0.017 x A - 2.746	0.0483 x H - 0.014 x A - 0.406
FEV1.0	0.1321 x H - 0.027 x A - 4.203	0.0686 x H - 0.021 x A - 0.794
FEV3.0	0.1600 x H - 0.031 x A - 5.245	0.0889 x H - 0.023 x A - 1.633
FEV1/FVC	-0.2210 x H - 0.140 x A + 103.64	-0.2819 x H - 0.109 x A + 107.38
FEF25 - 75	0.1143 x H - 0.031 x A - 1.864	0.0533 x H - 0.024 x A + 1.171
PEF	0.2388 x H - 0.035 x A - 5.993	0.1245 x H - 0.025 x A - 0.735
FEF25	0.2235 x H - 0.035 x A - 5.618	0.1092 x H - 0.025 x A - 0.132
FEF50	0.1753 x H - 0.015 x A - 5.400	0.0889 x H - 0.013 x A - 0.444
FEF75	0.1118 x H - 0.012 x A - 4.143	0.0 x H - 0.014 x A + 3.042

A: Age

H: Height in inches

Composite Norm Values

Selection of the Composite normals provides selected equations taken from other tables as follows:

Value	Equation Reference
FVC	Knudson
FEV1	Knudson
FEV3	Crapo
FEF25 - 75	Knudson
FEF75 - 85	Morris
FEF0.2 - 1.2	Morris
MVV	Crapo
SVC	Knudson (same as FVC)

Norm Values

Polgar Norm Values

The Polgar equations are valid for both children and adults in specific groups according to age as follows:

	Males	**Females**
	Age under 18 years	*Age under 18 years*
FVC	H(power 3)*0.0000071 +H(power 2) *0.00057 -H*0.0123 +0.14	H(power 3)*0.0000076 +H(power 2) *0.00048 +H*0.0112 +0.13
FVC0.5	H*0.076 +A*0.043 -3.05	
FEV1.0	H(power 3)*0.00000087 +H*0.00035 -H*0.0086 +0.1	H(power 3)*0.0000086 +H(power 2) *0.00035 -H*0.0086 +0.1
FEF25 - 75%	H*0.1109 -3.46	H*0.1109 -3.46
PEF	H*0.2219 -7.09	H*0.2219 -7.09
MVV	H*4.68 -A*1.8 -192.32	H*2.76 -A*3.4 -108.12
	Age 18 to 25 years	*Age 18 to 20 years*
FVC	H*0.1499 +A*0.0739 -6.887	H*0.1057 +A*0.0699 -4.447
FEV1.0	H*0.1318 +A*0.0636 -6.118	H*0.0892 +A*0.0694 -3.762
FEF25 - 75	H*0.1369 +A*0.0749 -6.199	H*0.0709 +A*0.1275 -2.801
PEF	H*0.1980 +A*0.1660 -8.061	H*0.1240 +A*0.1570 -3.920
FEF50	H*0.1379 +A*0.1150 -6.385	H*0.0732 +A*0.1111 -2.304
FEF75	H*0.1008 -A*0.0057 -4.242	H*0.0617 +A*0.2923 -4.401
MVV	H*4.68 +A*1.8 -192.32	H*2.76 +A*3.4 -108.12
	Age over 26 years	*Age over 20 years*
FEF3.0		H*0.1067 -A*0.0257 -2.745
FEF0.2-1.2	H*0.1090 -A*0.0470 +2.010	H*0.1450 -A*0.0360 -2.532
FEF25 - 75%	H*0.1471 -A*0.0363 -4.518	H*0.0531 -A*0.0344 +1.128
FEF75 - 85%	H*0.0130 -A*0.0230 +1.210	H*0.0250 -A*0.0210 +0.321
PEF	H*0.2390 -A*0.0350 -5.990	H*0.1240 -A*0.0250 -0.740
FEF25	H*0.0900 -A*0.0220 +2.726	H*0.0690 -A*0.0190 +2.147
FEF50	H*0.1737 -A*0.0366 -5.409	H*0.0681 -A*0.0289 +0.609
FEF75	H*0.0787 -A*0.0230 -2.483	H*0.0244 -A*0.0259 +1.118
MVV	H*3.03 -A*0.816 -37.9	H*2.14 -A*0.685 -4.87

A: Age

H: Height in inches

The remaining values are taken from the ITS equations.

Norm Values

Race Influences on Norm Values

According to the setting of the patients race the predicted values will differ. The differences are (according to ITS recommendations) as follows:

- When in the "Settings" menu **NONE** was set:

  All values are calculated according to the given formulas.

- When in the "Settings" menu **(W/B)** was set:

  W (White): values are calculated according to the given formulas (= 100%)

  B (Black): 85% of the given formulas

- When in the "Settings" menu **(C/H/B/A)** was set:

  C (Caucasian): values are calculated according to the given formulas (= 100%)

  H (Hispanic): values are calculated according to the given formulas (= 100%)

  B (Black): 85% of the given formulas

  A (Asian): 85% of the given formulas

CHAPTER 4

Data Storage and Transmission

Data Storage

Store Data in Memory

To store spirometry data in the built-in memory (e.g. for tests with PRE/POST medication), proceed as follows:

1. Enter patient data (important for later identification in the memory list).
2. Make tests.
3. After completing the tests, press the STORE DATA key. The message "FILE IS STORED" appears as confirmation of the saving.

NOTE: The values of the FVC, SVC, MV and MVV tests can be stored.

4. Return to the main menu with ESC.

Recall Data from Memory

To recall spirometry data from the memory, proceed as follows:

1. Press the RECALL DATA key.
2. Select file by moving the cursor with the arrow keys to the appropriate position.
3. Confirm selection by pressing the ↵ ENTER key.

NOTE: Only the patient data and measurement values can be viewed on the screen.

4. The complete test can be printed as described in Chapter 3 under "Printing out Test Curves and Measurement Results".

Delete Data from Memory

To delete spirometry data from the memory, proceed as follows:

1. Press the RECALL DATA key.
2. Select file by moving the cursor with the arrow keys to the appropriate position.
3. Confirm selection by pressing the ← DEL key. The message "DELETE FILE? (Y/N)" appears.
4. Confirm with **Y** (yes) or retract with **N** (no).
5. Return to the main menu with ESC.

Data Storage

Maximum Memory Capacity

The maximum memory capacity for the SP-10 is as follows:

- ≤ 60 patients (one test only)
- or 30 patients (3 FVC / 3 SVC / 1 MV / 1 MVV Test)
- or 30 patients (3 FVC / 3 SVC Pre & Post Test)
- or 30 patients (3 FVC / 3 SVC / 1 MV / 1 MVV Pre & Post Test)

Data Transmission

The SCHILLER SP-10 can only send spirometry data to a PC (SEMA). The units can be connected directly or can communicate over a telephone line by modem. Data transmission is facilitated via one of the standard serial interfaces on the back panel. For shorter distances and with a modem use the RS-232 Port 3 interface (max. 15 metres with 19'500 Baud). With longer cables the RS-422 interface (max. 1'200 metres) is recommended.

Only the spirometry data that is currently in the memory of the SP-10 can be sent.

Direct data sending to a connected PC (SEMA) is called **LINE** transmission and data sending over a *telephone* line is called **MODEM.**

- In spirometry mode only one type of line sending format (to SEMA) is to be selected in line mode called BLOCK. With block transmission the transmitted data is checked for errors and corrected accordingly.
- Two types of transmission protocols can be selected in modem mode called CCITT and BELL. These are standard modem protocols and are selected according to the type modem connected.

Other transmission settings that are applicable for both line and modem transmission are as follows:

Channel	Here the connector is selected for transmission.
Baud	This sets the speed of transmission - the higher the Baud rate the quicker the transmission. In good quality lines or short distance lines a high Baud rate can be set. When a lot of transmission errors occur a lower Baud rate should be selected.
Parity	This is a method of detecting errors in the transmission.
Stop	This is a method that the hardware uses to determine the start and end of sections of the message.

ALL THESE SETTINGS ARE LARGELY DEPENDENT ON THE PC THAT IS CONNECTED. THEY MUST BE THE SAME IN BOTH THE TRANSMITTING AND RECEIVING UNITS!

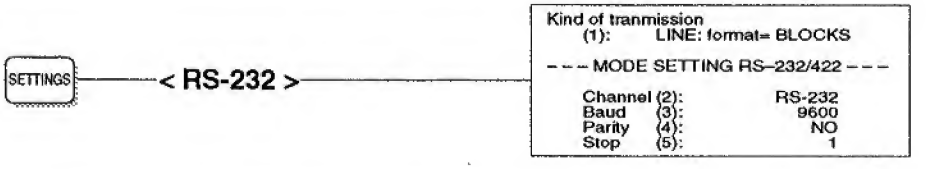
Data Transmission

Line Transmission

SEMA is the SCHILLER data management system for diagnostics which allows storage, processing and archiving of pulmonary function tests on a PC.

- **For the data transfer to SEMA only use *BLOCKS*.**

If your SP-10 is connected directly to a PC with SEMA, proceed as follows:



- Set the following parameters for line transmission:

LINE — Select line transmission and the format with key **1**. Set to: LINE: format = BLOCKS

Channel (2) — Use Key **2** to select the required channel. Select between RS-232 or RS-422 (normally RS-232).

Baud (3) — Use Key **3** to select the required baud rate. The following values are available: 75, 150, 300, 600, 1200, 2400, 4800, 9600, 19200, 38400, 76800, 153600.

Parity (4) — Key **4** selects the parity. The available choice is either EVEN, ODD or NO (normal position NO).

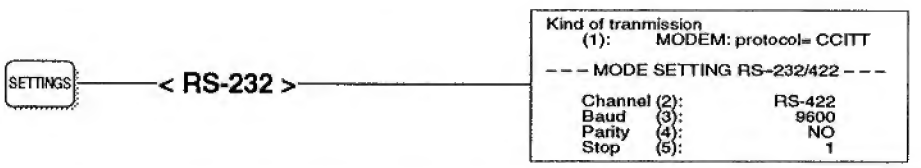
Stop (5) — The length of the stop bit is determined by pressing key **5**. The available choice is either 1, 1.5 or 2 (normal position 1).

NOTE: Check that these settings are the same as the PC to which the SP-10 is connected.

Data Transmission

Modem Transmission

If your SP-10 is connected over a modem to a PC, proceed as follows:



- Set the following parameters for MODEM transmission:

MODEM — Select line transmission and the format with key **1**. The following two formats are selectable:
MODEM: protocol = CCITT
MODEM: protocol = BELL
Select in accordance with the protocol of your telephone exchange.

Channel (2) — Use Key **2** to select the required channel. Select between RS-232 or RS-422 (normally RS-232).

Baud (3) — Use Key **3** to select the required baud rate. The following values are available: 75, 150, 300, 600, 1200, 2400, 4800, 9600, 19200, 38400, 76800, 153600.

Parity (4) — Key **4** selects the parity. The available choice is either EVEN, ODD or NO (normal position NO).

Stop (5) — The length of the stop bit is determined by pressing key **5. The** available choice is either 1, 1.5 or 2 (normal position 1).

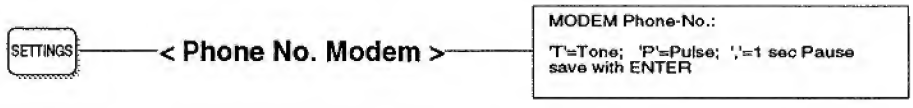
Selections 2 to 5 are the same as with line transmission.

NOTE: Check that these settings are the same as the device to which the SP-10 is connected.

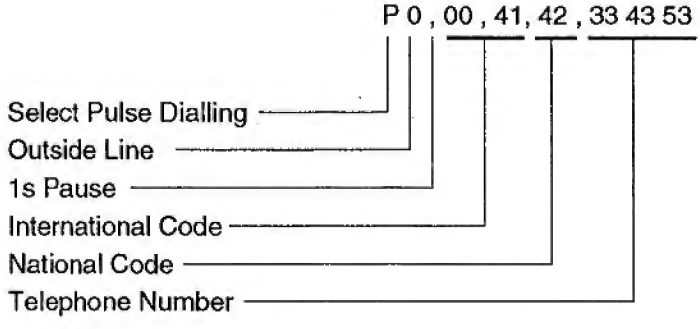
Data Transmission

Enter Phone Number for Modem Transmission

- To enter the Phone number of the reception unit, proceed as follows:



A typical example of a telephone number can be as follows:



- Before entering the telephone number the type of dialling must be entered. This is determined by the type of telephone exchange. All modern exchanges now use tone dialling; older exchanges use pulse dialling. If in doubt select pulse.

- If it is necessary to enter a pause in the dialling sequence then enter a comma. The comma gives a one second pause; if a longer pause is required, two or more commas can be entered. This may be required for example, if you have to wait for an outside line. To give the exchange time to set up the connection, it is also a good idea to insert a pause after a national or international code.

- Press **ENTER** to confirm the settings and return to the main menu.

Data Transmission

Send Data

To send the spirometry data that is currently stored in the memory proceed as follows:

- Check that the cable is connected to the SP-10 (RS-232 Port 3 or RS-422).
- Be sure that all the setups are done and correct.
- Press the SEND DATA key after the tests are completed.

NOTE: If stored data in the memory is to be sent, it must first recalled on the screen. It can then be sent by pressing SEND DATA.

Error Messages

If the data can not be sent an error message will be displayed in the status field.

A list of possible error messages and their possible causes together with solution possibilities is given below:

SERIAL LINK TIME-OUT	This indication appears if no signal is received from the remote unit (after approximately 30 seconds). Check that the remote unit is switched on and set to the correct parameters. Check the correct setup in both connected units (=> **SETTINGS** key). Check that the connecting cable is plugged in correctly. Check the integrity of the cable assemblies (on both units). If using a modem ensure that it is communicating with the remote modem.

Data Transmission

TX-ERROR (PARITY)	This indicates a parity error. Check that the parity is set correctly in both receiving and transmitting units (=> **SETTINGS** key). If there is a parity error it indicates that the data may be faulty. Select other test data and re-transmit. Carry out the RS self test procedure.
TX-ERROR (OVERRUN)	This indicates a system timing error. Carry out the RS self test (=> **SETTINGS / 5**).
TX-ERROR (FRAMING)	This indicates a transmission error or that the baud rate is not the same setting in both units. Check that the baud rate is set correctly in both units (=> **SETTINGS** key). Check that the connecting cable is plugged in correctly. Check the integrity of the cable assemblies (on both units). If using a modem ensure that it is communicating with the remote modem.
DATA SET NOT READY!	This is a general fault indication. Check that the remote unit is switched on and set to the correct parameters. Check that the connecting cable is plugged in correctly. Check the integrity of the cable assemblies (on both units). If using a modem ensure that it is communicating with the remote modem.
NO DATA IN MEMORY!	A spirometry data transmission has been attempted, but no data is stored in the units memory. Store a spirometry test in the memory and attempt the transmission again. If the same message appears, contact your SCHILLER agent.

CHAPTER 5

Maintenance, Testing, Trouble Shooting

Replacing the Recording Paper

A red strip on the bottom edge of the recording paper indicates that it needs to be replaced. When this strip appears, there are about fifteen A5 pages left. We recommend that the paper be replaced as soon as this indication appears. Should the paper run out completely, then an audible alarm is initiated and the message "REFILL PAPER!" appears on the display.

To replace the paper, proceed as follows:

- By pressing the key REPLACE PAPER, the paper tray slides out automatically.
- Remove any remaining paper from the paper compartment.
- Take a new pack of recording paper and place it into the paper compartment with the grid side upper most and with the black markings at the top of the paper towards the back of the unit.
- Pull the first sheet out of the paper tray so that it is over the roller.
- Press REPLACE PAPER again and the paper tray slides in automatically.

When printing is restarted, the warning message will be removed from the display.

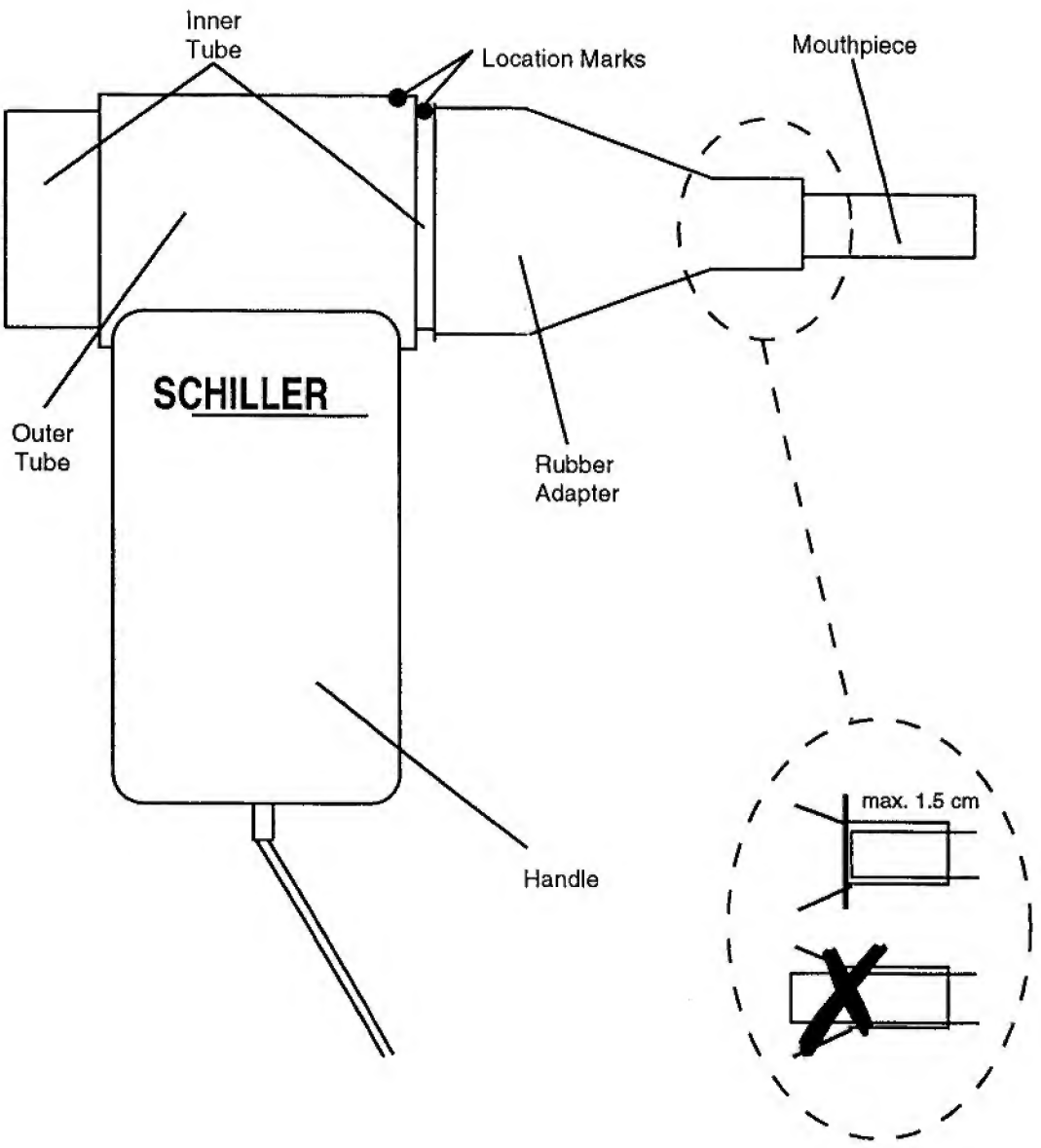
NOTE: *WELCH ALLYN can only guarantee impeccable printing quality if the original chart paper or paper of equal quality is used.*

Cleaning the Casing

The casing of the SCHILLER SP-10 should be cleaned with a soft cloth on the surface only. **Switch the unit off before cleaning.**

NOTE: *Do not, under any circumstance, immerse the apparatus into a cleaning liquid or sterilize with hot water, steam, or air.*

Flow Sensor SP-110



Flow Sensor SP-110

Cleaning and Sterilising

The utmost attention must be paid to the cleanliness of the flow sensor. Because the patients must breathe through the nozzle (inhaling as well as exhaling), it is important that the mouthpiece and filter be renewed and the measuring tube painstakingly cleaned and sterilised before the next patient uses the device.

To clean the flow sensor, proceed as follows:

- Remove and discard the mouthpiece.
- Remove the rubber adapter by pulling it away from the inner tube.
- Remove the inner tube of the flow sensor by pushing it out of the outer tube in the direction of the red location marks. Once the tube has been pushed half way it can be pulled out from the other side.
- Unscrew the two halves of the inner tube and remove and discard the filter.
- Clean and sterilize all parts of the inner tube, the rubber adapter and the inside of the outer tube with one of the following products or a product of equal quality:

- Kohrsolin
- Lysoform

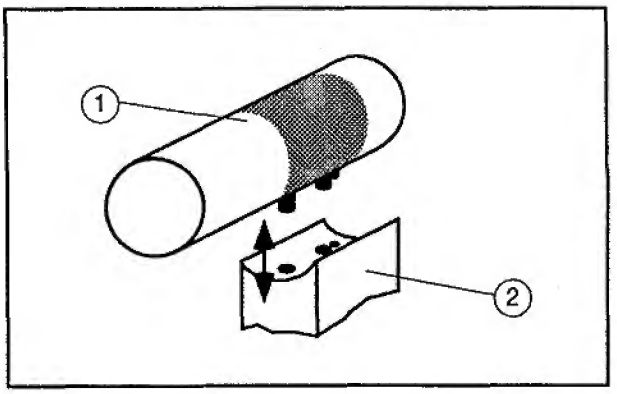
- The cable and handle can be wiped with soapy water.

To reassemble the flow sensor, proceed as follows:

- Insert a new filter into the inner tube so that it sits on the inner lip of the half with the red location mark.
- Carefully screw the two halves of the inner tube together making sure that the filter is not displaced.
- Locate the end of the inner tube into the end of the outer tube and push it gently but firmly until the shoulder of the inner tube makes contact on the outside edge of the outer tube. *The two red location marks must be together.*
- Fit the rubber adapter by placing its wider end over the end of the inner tube with the red location mark.
- Insert a new mouthpiece (max. 1.5 cm) into the end of the rubber adapter.

The flow sensor is now ready for use.

Flow Sensor SP-150



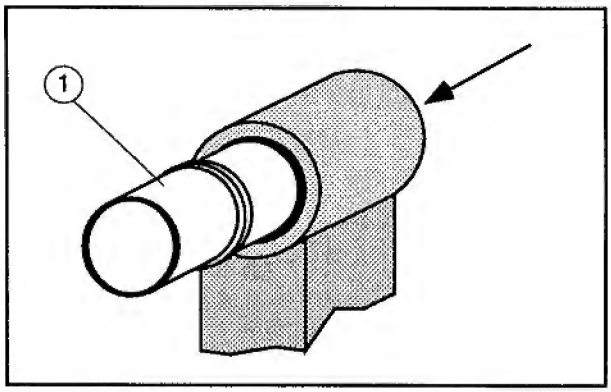
1. Remove disposable mouthpiece (1) by gently but firmly pulling it away from the handle (2).

2. Discard the complete assembly.

3. Position new disposable mouthpiece **(Part No. 2.100077)** and gently but firmly click it in position.

NOTE: The disposable mouthpiece can only be positioned in one direction and no force is necessary to insert it on the handle.

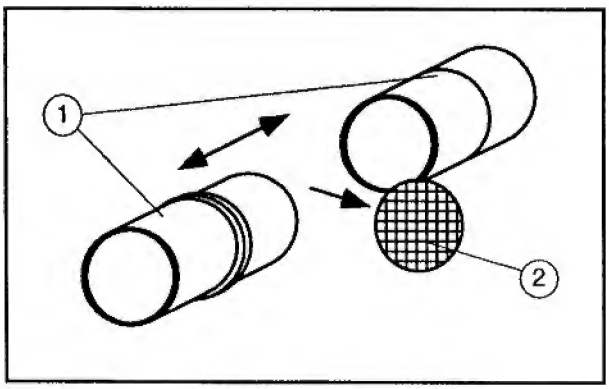
Flow Sensor SP-20



1. Slide out the combined filter/mouthpiece assembly (1).

NOTE: This is only possible in one direction.

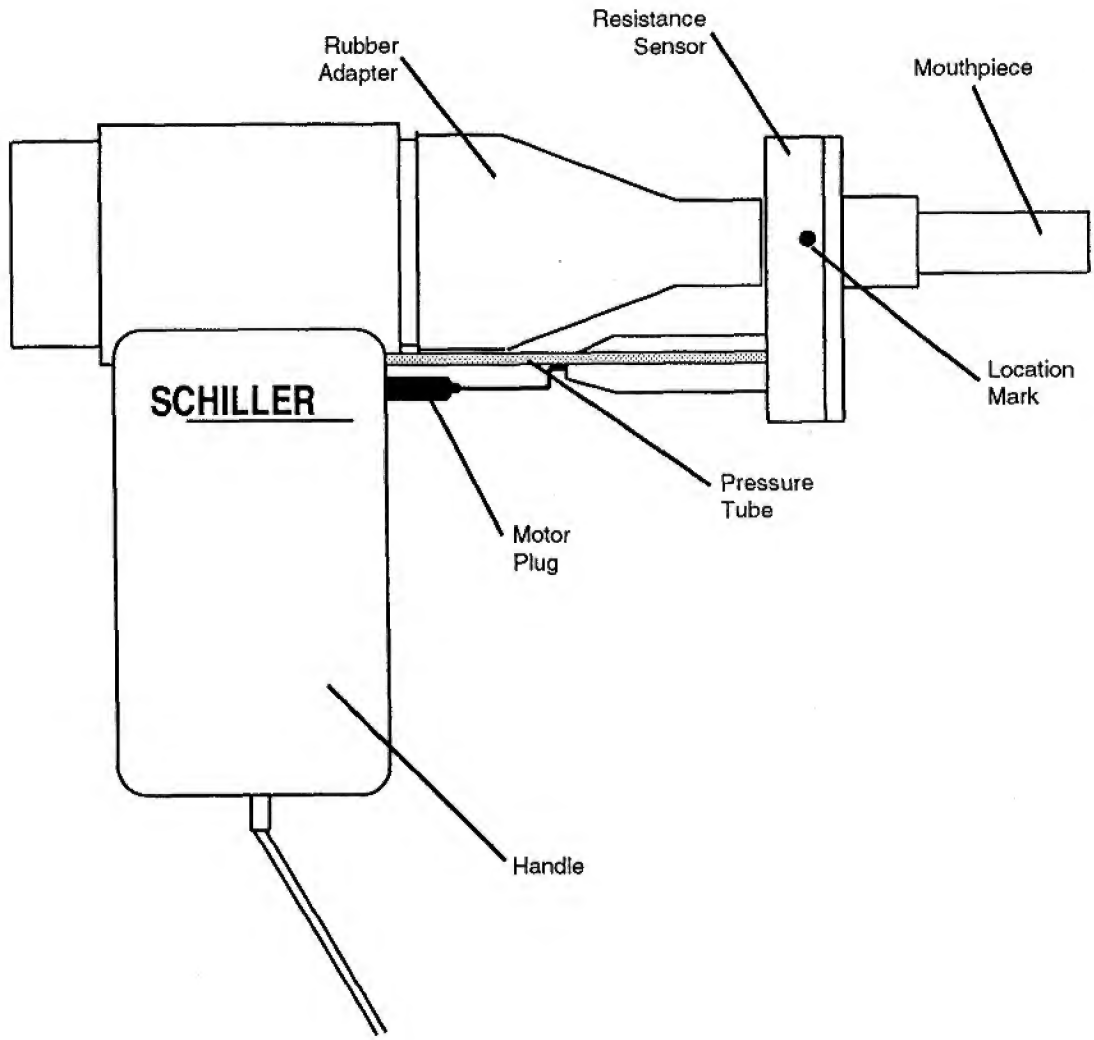
2. Unscrew the assembly.



3. Remove and discard filter (2).
4. *Clean and disinfect the assembly after every patient.*
5. Insert a new filter **(Part No. 2.100123)**.
6. Carefully screw the two halves of the assembly together again. *Make sure that the filter is not displaced.*
7. Push the combined filter/mouthpiece assembly gently but firmly into the outer tube until it makes contact on the outside edge of the outer tube.

NOTE: The assembly can only be fit in one direction.

Flow Sensor SP-110/R with Resistance Sensor



Flow Sensor SP-110/R with Resistance Sensor

Cleaning the Resistance Sensor SP-110/R

With each resistance test, a buildup of condensation is created within the resistance sensor of the flow sensor. This should be wiped dry after each patient.

To clean the resistance sensor, proceed as follows:

- Remove and discard the mouthpiece.
- Disconnect the pressure tube and motor plug from the handle.
- Pull the resistance sensor out of the rubber adapter.
- Separate the two halves of the resistance sensor, making sure that the shutter does not fall out.
- Clean and sterilize all parts of the inner tube, the rubber adapter and the inside of the outer tube with one of the following products or a product of equal quality:

- Kohrsolin
- Lysoform

NOTE: *Before starting tests with a new patient, the main part of the flow sensor should also be thoroughly cleaned and sterilised as described before.*

To reassemble the resistance sensor, proceed as follows:

- Check that the shutter is in place and reassemble the two halves of the sensor making sure that the two air tube apertures are on the same side. Press lightly until the two halves click together.
- Insert the air tube into the rubber adapter ensuring that the pressure tube and motor plug are on the under side and pointing in the direction of the flow sensor handle (red location mark to the left).
- Slide the pressure tube over the connection on the handle of the flow sensor.
- Plug the motor plug into the socket on the handle of the flow sensor.
- Insert a new mouthpiece.

The resistance sensor is now ready for use.

User Checks

Self-Test of the Unit

Each time the unit is switched on, a self-test is performed to check all the functions.

Technical Safety Check

At 12 monthly intervals, the unit should undergo a technical safety check. The extent of this check should include the following:

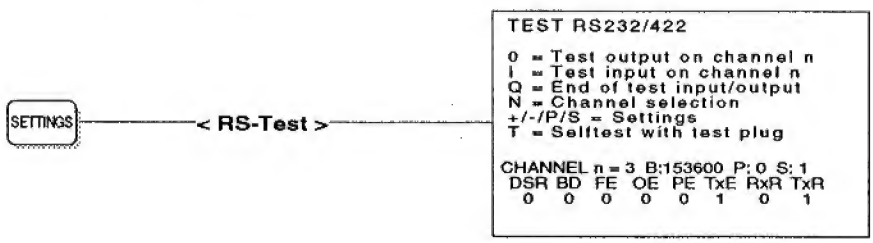
- Visual inspection of the unit and cables.
- Electrical safety tests according to IEC 601-1.
- Functional tests according to the Service Handbook.

User Checks

Test Output Channels (RS-Test)

NOTE: The tests in this menu, in particular the self test (key T) which has to be carried out with a special test plug, are intended for use by authorised service personnel only.

- First connect the SCHILLER SP-10 to an external unit that can send or receive data.
- To test the transmission channels, proceed as follows:



First define the transmission channel (B, P and S) before it is to be tested.

- Select the transmission channel that is to be tested by pressing the key **N** (set to either 3 or 4).
- Change the baud rate with the keys YES + or NO −.
- Change the parity and the stop bits with the keys **P** and **S**.

To carry out an input test on the selected channel, press the key **I**. To carry out an output test on the selected channel, press the key **O**.

- With the **output test** the message "TEXT OUTPUT" appears as last line.
- With the **input test** a special display appears. It shows the last three lines of the previous display with the received text characters.

To quit either of the above test sequences, press **Q**.

CHAPTER 6

Technical Data

Dimensions (l/w/h):	320 x 264 x 74 mm
Weight:	Approx. 4.7 kg
Power supply requirements:	110 / 130 / 220 / 240 VAC,50 / 60 Hz
Power consumption:	13 to 30 VA
Battery:	Lead-acid,2 x 12 V
Printing process:	High-resolution thermal printhead, 8 dots per mm (amplitude axis),40 dots per mm (time axis) @25 mm/s
Paper speed:	2.5 / 5 / 10 / 12.5 / 25 / 50 / 100 mm/s
Chart paper:	Thermoreactive, Z-folded,perforation for A5 format
Liquid crystal display:	Backlighted liquid crystal display for monitoring and alphanumeric information
	Resolution: 640 x 480 dots;viewing angle adjustable
Safety standards:	BF according to IEC and complying with the following:
	RL 93/42/EEC
	EN 60601-1:1990
	IEC 601-1
	pr EN 1441:1994
	IEC 513:1994
	EN 55011 /IEC 801
Protection class:	I according to IEC, VDE, SEV (with internal battery power)
	IIa according to RL 93/42/EEC
Environmental conditions:	Temperature, operating: 10° to 40° C Temperature, storage: -10° to 50° C Relative humidity: 15 - 85% (non-condensing)
Keyboard:	Splashproof keys

Technical Data

Pulmonary Functions

Method of Measurement:	Pneumotachometer
Measurement Ranges:	Flow: 0 to ±14 l/s;Volume: 0 to ±11 litres
Measurement Accuracy:	±2%
Flow Impedance:	Less than 0.5 mbar * s/l at 10 l/s
Measured Values:	VC, ERV, IRV, TV, FVC, $FEV_{0.5}$, $FEV_{1.0}$, $FEV_{3.0}$, $FEV_{0.5}$/VC, $FEV_{1.0}$/VC, $FEV_{3.0}$/VC, $FEF_{0.2-1.2}$ (litres), $FEF_{25-75\%}$, $FEF_{75-85\%}$, PEF, $MEF_{75\%}$, $MEF_{50\%}$, $MEF_{25\%}$, MV, MVV, FIVC, $FIV_{1.0}$, $FIV_{1.0}$/FIVC, $FIV_{1.0}$/FVC, PIF, $MIF_{50\%}$. Comparison pre/post medication possible.
Prediction Equation:	Adults:ECCS / Austria / Berglund / Finnish / Indian / Morris / Crapo / Knudson / Knudson76 / Polgar Children:Quanjer & Tammeling / Austria / Indian / Knudson / Knudson74 / Polgar

Video Connector

Connector for external monitor.

D sub, 15 pole, High-density, female:

Resolution:	640 x 480 dots
Input signals:	Horizontal sync.: TTL (positive) Vertical sync.:TTL (negative) Video: 0 to 0.7 V
Scanning frequency:	Horizontal: 31.3 kHz Vertical: 60 Hz
Pin Connections:	Pin 2 Video Pin 5 Test Pin 7 Video GND Pin 9 D CLK Pin 10 Sync GND Pin 11 DISP Pin 13 H-SYNC Pin 14 V-SYNC

Technical Data

Serial Interfaces

RS-232 (V24) Interfaces (Interfaces No. 1, 2 and 3)

Protocol:	Asynchronous
Baud Rate:	75 to 153600 Baud
Byte Format:	1 start bit, 8 data bits 0 or 1 parity bit (+ or -), programmable 1 / 1.5 / 2 stop bits, programmable
Transfer Control:	By means of DTR, DSR, CTS, RTS
Connection Socket:	3 x D subminiature (9 pole female), wired as DTE (Data Terminal Equipment).
Pin Connections:	Channel 1, 2, 3: Pin 3 TXD1 O (output data) Pin 2 RXD1 I (input data) Pin 7 RTS1 O (request for output) Pin 8 CTS1 I (ready for output) Pin 6 DSR1 I (transfer unit ready) Pin 4 DTR1 O (SP-10 ready) Pin 5 GND (ground)

RS-422 Interface (Interface No. 4)

Protocol:	Asynchronous
Baud Rate:	75 to 15600 Baud
Byte Format:	1 start bit, 8 data bits 0 or 1 parity bit (+ or -), programmable 1 / 1.5 / 2 stop bits, programmable
Transfer Control:	None
Connection Socket:	1 x D-sub, 9 pole
Pin connections:	Pin 1 GND Pin 2 TXC + Pin 3 TXC - Pin 4 RXC + Pin 5 RXC - Pin 6 RXD + Pin 7 RXD - Pin 8 TXD + Pin 9 TXD -